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University of Southampton

Faculty of Environmental and Life Sciences

Health Sciences

A mixed methods study to determine the feasibility of providing finger foods for patients after stroke in hospital

DOI

by

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Thesis for the degree of Doctor of Philosophy

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Abstract

Faculty of Environmental and Life Sciences

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A mixed methods study to determine the feasibility of providing finger foods for patients after stroke in hospital

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Milly Heelan

Many people in hospital after stroke experience eating difficulties and are at risk of reduced food intake. Finger foods (foods that can be easily transferred from the plate to the mouth without the need for cutlery) have the potential to increase food intake and enable mealtime independence. However, there is little published evidence evaluating the use of finger foods in a hospital, and the components of a well-designed trial evaluating this intervention are unclear.

This thesis aimed to develop a finger food menu and subsequently evaluate the feasibility and acceptability of using it for people in hospital after a stroke.

A finger food menu was developed from menu items already offered in the hospital, consulting with clinical and catering teams and patient representatives. The menu was offered to patients over two lunchtime meals and compared with the standard lunchtime menu. A mixed-methods study was used to assess feasibility and acceptability.

Quantitatively, expected recruitment rates were met, with thirty-one patients recruited (mean age 80, SD 8.5). Retention to the study was limited, with 40% of patient participants lost to follow-up. Attrition was attributed to participants being discharged from the ward. Dietary intake measures showed good interrater reliability. A cost consequence analysis was performed which identified the direct and indirect costs of delivering the finger food menu.

Qualitatively, mealtime observations showed it was possible to deliver the finger food menu on the stroke rehabilitation ward, supported by an internal facilitator. Patient and staff interviews showed that, overall, participants found the finger food menu acceptable.

Findings demonstrated that it was feasible and acceptable to develop and use a finger food menu on a stroke rehabilitation ward however, the limited sample size and high rate of missing data limit the ability to generalise the results. A future trial is warranted to evaluate the effectiveness of a finger food menu in hospitals. It should engage clinical and catering teams, and patient representatives to shape the intervention to the setting and develop a robust study design.

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Research Thesis: Declaration of Authorship

Print name: Milly Heelan

Title of thesis: A mixed methods study to determine the feasibility of providing finger foods for patients after stroke in hospital

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. Parts of this work have been published as:
8. Heelan, M., Prieto, J., Roberts, H., Gallant, N., Barnes, C. and Green, S., 2019. The use of finger foods in care settings: an integrative review. *Journal of Human Nutrition and Dietetics*, 33(2), pp.187-197.

Signature: ....Date: March 2021

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Definitions

Dysphagia - The medical term for swallowing difficulties (Chen et al. 2019) or difficulties with eating and drinking which often occur with other health conditions such as stroke (RCSLT 2021).

Eating difficulties – Impairments which can influence a person's ability to consume food and enjoy eating, including ability to prepare and transfer food from the plate to the mouth. Eating difficulties can be as a result of impairment to cognitive, motor and sensory functions within the context in which swallowing occurs (Shune and Moon 2016).

Feasibility study - A study completed prior to a main study to establish whether a larger study can be delivered (Williams 2016).

Finger food - foods presented in a form that are easily picked up with the hands and transferred to the mouth; without the need for cutlery (Department of Health 2014; Buckinghamshire Health Care NHS Trust 2015)

Hospital ward – 'A group of hospital beds with associated treatment facilities managed as a single unit for the purposes of staffing and treatment responsibilities.' (Health and Social Care Information Centre 2021)

Hospital mealtime –A time reserved for an eating episode whilst in hospital. A hospital mealtime is a complex process with complexity arising from both the interrelated components within food service and health care systems and the patient variability.

Person after stroke – Person who has experienced a stroke. A stroke is defined by the World Health Organisation as: 'A clinical syndrome typified by rapidly developing signs of focal or global disturbance of cerebral functions, lasting more than 24 hours or leading to death, with no apparent causes other than of vascular origin' (Mackay and Mensah 2004)

Stroke rehabilitation ward – An inpatient hospital ward devoted to rehabilitation for people after stroke. It is staffed by a team of nurses, doctors, physio therapists, occupational therapists, dietitians, psychologists and speech and language therapists. The study ward for this study was a stroke rehabilitation ward.

Ward Host - A member of staff employed by the hospital Trust catering provider. Typically, they assist with making menu choices, serving and delivery of meals.

Abbreviations

BDA	British Dietetic Association
BMI	Body Mass Index
CASP	Critical Appraisal Skills Programme
CDRF	Clinical Doctoral Research Fellow
CONSORT	Consolidated Standards of Reporting Trials
CQC	Care Quality Commission
GDPR	General Data Protection Regulation
HCPC	The Health and Care Professions Council
HCA	Healthcare assistant
HRA	Health Research Authority
ICC	Intraclass Correlation
IDDSI	International Dysphagia Diet Standard Initiative
MCA	Mental Capacity Act
MDT	Multidisciplinary team
MRC	Medical Research Council
MUST	Malnutrition Universal Screening Tool
NHS	National Health Service
NICE	National Institute of Health and Care Excellence
NIHR	National Institute for Health Research
NIHSS	National Institute of Health Stroke Score
PIS	Patient Information Sheet
PLACE	Patient-Led Assessments of the Care Environment
PPI	Patient and Public involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
R & D	Research and Development
RCT	Randomised Control Trial
SD	Standard Deviation

Abbreviations

SLT	Speech and Language Therapist
SN	Staff Nurse
SSNAP	Sentinel Stroke National Audit Programme
TBI	Traumatic Brain Injury
UK	United Kingdom

Chapter 1 **Introduction and background**

1.1 Introduction

Older people in hospitals are one reported group of patients who have difficulties participating in mealtimes and require support with eating (Vizard and Burchardt 2015). Hospital food can have a direct impact on patient experience, with the presentation of food linked with the likelihood of eating (The Patients Association 2020). Relatives of older people in the hospital frequently report inadequate amounts of both appropriate food and support for people unable to feed themselves (Age Concern 2006; Age UK 2010; Francis 2013). A stroke can lead to an increased dependence on support with eating, due to the high prevalence of dysphagia, eating difficulties and physical or cognitive impairments (Westergren et al. 2001b; Poels et al. 2006; Carlsson and Hagg 2015). NHS Trusts have an obligation to provide adequate food, drink and appropriate support to meet the nutrition and hydration needs of any person staying overnight in hospital (Care Quality Commission 2017). However, one in three people in hospital in England is at risk of malnutrition (Elia 2015).

Finger foods (foods that can be easily picked up with the hands and transferred to the mouth, without the need for cutlery) have the potential to increase food intake and improve people's dignity and independence during mealtimes. Finger foods are variably used in UK hospitals and current evidence for their use in hospitals is sparse and anecdotal (Heelan et al. 2019).

This thesis aims to develop a finger food menu intervention and conduct a feasibility study to evaluate the feasibility and acceptability of using the intervention for people in hospital after a stroke. The idea of using foods that do not require cutlery appears a simple solution to support eating and drinking; however, to provide this in a complex hospital mealtime setting, with multiple inter-relating factors, requires a systematic approach to evaluation, which is presented within this thesis.

1.2 Background

Chapter one presents the background to this thesis, including the challenges of undernutrition in hospitals and the multifactorial impacts of dysphagia, eating difficulties and ward environment on a patient's food intake. This chapter examines the key policy and institutional drivers for reducing undernutrition in hospitals within the NHS in England and contextualises these in the wider literature. A full introduction to finger foods is provided at the end of the chapter, with an indication of where they are currently used and barriers to using them in health settings.

1.3 Introduction to malnutrition

1.3.1 What is malnutrition?

For this thesis, malnutrition is used to mean undernutrition: 'a state in which a deficiency of energy, protein and other nutrients causes measurable adverse effects on tissue, body form and function and clinical outcomes' (BAPEN 2018, p.1).

1.3.2 What causes malnutrition?

Causes of malnutrition in hospitals can be multifactorial and include acute illness or disease, dislike of food, and psychosocial or environmental factors e.g., poor quality or presentation of meals or lack of assistance with eating (British Dietetic Association 2017). Hospitalisation can lead to further deterioration of nutritional status (Laur et al. 2015), which can have negative outcomes on functional rehabilitation. Physiologically, the energy requirements of individuals can depend on multiple factors, such as age, gender body composition, current and past nutritional status and basal metabolic rate (BMR) which is essential to maintain life functions. During acute illness the BMR of an individual can increase, which if left uncontrolled can lead to weight loss and malnutrition (Weekes 2007).

Multiple modifiable factors impact malnutrition including hospitalisation, eating dependency, physical function, poor self-perceived health, poverty and poor appetite, however, strong robust evidence is lacking for the majority of determinants (O'Keeffe et al. 2019). Mealtimes and food habits can vary widely across patients. When individuals are away from their typical environment the disruption to cultural norms can increase the risk of reduced oral intake. For example, food in institutional settings such as hospitals is based upon a food tradition designed by nutritionists and large-scale servings (Axelsson et al. 1984) and cannot always meet an individual's cultural needs (BAPEN 2018).

1.3.3 What are the consequences of malnutrition?

Malnutrition has wide implications and can affect financial, clinical, physiological, psychological and social outcomes and can be both a cause and a result of ill health (NHS England et al. 2015).

In England, it was estimated that malnutrition would cost the National Health Service (NHS) thirteen billion pounds per annum by 2020 (Forsey 2018). Overall, the cost of treating a malnourished patient is two to three times more than treating a non-malnourished patient (Elia 2015). This contributes to increased pressure and demand for services within the NHS which is forced to perform under strict budgets (NHS England 2017).

Clinical consequences of malnutrition can include increased risk of infection, delayed wound healing and deterioration of muscle mass and weakness, which in turn can affect the activities of daily living (BAPEN 2018). Further complications of malnutrition can be linked to impaired respiratory functions, impaired cardiac function, impaired immunity, reduced renal function and in the most severe cases linked to mortality, with people after a stroke or recently hospitalised a population at highest risk (Hickson and Smith 2018).

In addition to physical consequences, undernutrition can also impact psychological and behavioural outcomes causing apathy, depression, introversion, self-neglect and deterioration in social interactions (Gibney et al. 2005; BAPEN 2018). The impact on mood, frequently reported as depression, can manifest as a reciprocal relationship. Symptoms of depression can lead to reduced appetite as well as undernutrition contributing to depression (Hickson and Smith 2018).

Socially, malnutrition can cause individuals to require increased care needs after discharge from hospital, increased healthcare costs and reduced levels of productivity. The impact of undernutrition on health-related quality of life can result from physical and cognitive changes increasing risks of infection, longer hospital stays and increased dependency with activities of daily living (Rasheed and Woods 2013).

1.3.4 Stroke and malnutrition

Dietary intake has long been associated with stroke both in terms of the development of this condition and the impact following stroke (Iacoviello et al. 2018). One group at particular risk of malnutrition are people after stroke. In this population, malnutrition following admission to hospital can increase the risk of ongoing undernutrition (Chen et al. 2019). Although rates of malnutrition in people after stroke is poorly recognised, its prevalence on admission to hospital is estimated at 20% (Lamb et al. 2009), increasing to up to 62% post stroke (Foley et al. 2009).

People after stroke can require a prolonged hospital stay. Many patients in hospital do not consume all of the food provided for them and it has been estimated that reduced energy and protein intake across elderly patient groups result in high levels of food waste (over 40%) (Barton et al. 2000).

Stroke associated dysphagia can be associated with a higher risk of malnutrition as the normal dietary intake of a person is affected (Chen et al. 2019). People after stroke, who have difficulty independently preparing food and therefore require assistance, are at increased risk for reduced oral intake and risk of undernutrition (Saletti et al., 2000; Westergren et al., 2001; Westergren et al., 2002a). People with eating difficulties associated with the oral preparatory phase of swallowing can become dependent on others, commonly associated with reduced intake and malnutrition (Forsey 2018).

Reduced nutritional intake has been adversely associated with a person's mental performance and adversely impact rehabilitation tasks (Klinke et al. 2013). Malnutrition in patients post stroke can lead to higher rate of infection, pressure sores and longer hospital stays (Zielińska-Nowak et al. 2021). Psychosocial and behavioural outcomes can influence stroke recovery, with depression associated with a poorer health related quality of life and influencing functional recovery (Donnellan et al. 2010). Adequate nutrition is fundamental in supporting post stroke recovery and is considered one of the most important factors to influence post stroke rehabilitation effectiveness (Zielińska-Nowak et al. 2021).

1.4 Eating difficulties in people after stroke

People with neurological impairment are one of the largest groups to experience eating difficulties (Beck et al. 2019), appearing in 40% to 80% of the population (Westergren et al. 2001b; Poels et al. 2006; Carlsson and Hagg 2015). Stroke can result in neurological impairment which can cause multiple deficits in relation to eating, including swallowing difficulties, upper limb difficulties and cognitive changes. Eating can also be impacted by gustatory and olfactory changes and motivation which can increase the risks of malnutrition.

1.4.1 Dysphagia in people after stroke

Dysphagia is the term for swallowing difficulties (Chen et al. 2019). Much of the literature on stroke and eating utilises the term 'eating difficulties' for people after stroke, when describing the impairment to cognitive, motor and sensory functions and the context in which swallowing occurs (Shune and Moon 2016).

Impairment to the swallowing process naturally impacts a person's ability to eat and drink. The swallowing process is highly complex, involving innervation from over 50 muscles and nerves. Safe and effective swallowing requires co-ordination of oral, pharyngeal, laryngeal and respiratory structures (Shune and Moon 2016). The swallowing process includes four phases: oral preparatory phase, oral phase, pharyngeal phase and oesophageal phase further described in Table 1-1

(Matsuo and Palmer 2008). Neurological damage from a stroke can result in impairment to any one or more of these phases leading to dysphagia.

Table 1-1 Description of four phases of the swallowing process

Swallow phase	Description
Oral preparatory phase	Sensory recognition of food approaching mouth, food is manipulated, tasted, and broken down into a consistency ready for swallowing
Oral phase	Tongue propels the food or fluid bolus backward
Pharyngeal phase	Reflexive stage of swallowing, where the bolus moves through the pharynx
Oesophageal phase	Bolus moves through the oesophagus and enters the stomach.

The more recent inclusion of the oral preparatory phase is of interest to this thesis, as finger foods are one intervention that may support difficulties with this phase. The oral preparatory phase includes the preparation and mastication of the bolus for swallowing and has meant that the swallowing process has been regarded as ‘The process model of feeding’, (Hiiemae and Palmer 1999; Matsuo and Palmer 2008). This phase encompasses more traditional aspects to eating and feeding meaning that people with oral preparatory stage swallowing difficulties may also be classified as those with ‘eating difficulties’. Westergren et al. (2001a) describe eating difficulties as difficulties that negatively interfere with the preparation and intake of food or drinks, linking to impairments seen within the oral preparatory phase.

1.4.2 Symptoms of eating difficulties in people after stroke

Physical eating difficulties such as difficulties with transporting or cutting up food can manifest following stroke. These include reduced ability to position in an upright position, hemiparesis or hemiplegia of the upper limbs, or limb apraxia causing difficulties organising, planning and performing voluntary motor movements (Wu and Lin 2015), manipulating cutlery (Intercollegiate Stroke Working Party 2016) and transporting food to the mouth (Poels et al. 2006).

Cognitive changes after stroke can cause difficulties with remembering the eating task, impact the ability to initiate a meal, reduced attention to mealtimes, or impaired ability to perform executive functioning tasks such as controlling speed and quantity to eat (Ertekin 2011). Perceptual changes, such as the ability to see food on the plate can also impact on a person’s ability to transfer food from the plate to the mouth (Klinke et al. 2013). In addition, stroke can affect a person's ability to recognise, use or manipulate objects such as cutlery, or recognise food in front of them (Poels et al. 2006).

Changes that are unobservable such as gustatory changes and olfactory changes are also prevalent in people after stroke and impact on eating (Heckmann et al. 2005; Wehling et al. 2015). An interview study to investigate patients' perceptions of eating difficulties after stroke showed that sensory loss within the oral cavity resulted in some participants being unaware of food temperature, food leaking or dribbling from the mouth or food pocketing in the cheek (Perry and McLaren 2003). These changes are shown to alter food enjoyment, impact appetite and correlate with social isolation, depression and mood changes (Croy et al. 2014).

Lack of motivation to eat following stroke is well documented (Woods and Begg 2015). However, considering food intake as a behaviour that is motivated is complex, as so many factors influence motivation to eat (Woods and Begg 2015). Eating difficulties due to stroke (described in this section) can all influence motivation to eat through a range of non-homeostatic and homeostatic mechanisms. Offering food in a form that is acceptable to a person is likely to enhance motivation to eat by addressing some of the difficulties highlighted.

1.4.3 Assessment of eating difficulties for people after stroke

For many people after stroke, eating difficulties can impact a multitude of factors from reduced nutritional intake, longer hospital stays and recovery time and social relations and exist beyond the acute stage of stroke (Perry and McLaren 2001). Assessment of eating difficulties is important to support the early identification. Evidence-based guidelines recommend the use of screening and assessment of both malnutrition risk and swallow function using reliable and valid tools (NICE 2019). Westergren (2006) also suggests screening of eating difficulties should be included to support optimal nutrition and eating situation for a person after stroke.

Screening can be used to initially detect eating difficulties after stroke which may require further assessment (Westergren 2006). Screening is defined by Westergren (2006) as a simple process to identify those who are having difficulties with eating. This compares with an assessment which is more of an in depth, complex process involving the use of multiple parameters and sometimes invasive instruments (such as a video fluoroscopy study of swallowing).

A systematic review by Westergren (2006), which aimed to capture and evaluate peer-reviewed published literature about screening methods for bedside detection of eating difficulties among persons with stroke, showed there were two peer-reviewed, published methods for screening of eating difficulties. The methods described by McLaren and Dickerson (2000) and Westergren et al.

(2002b) both used observation scales focusing on items relating to communication, vision/perception, arm movement, posture, attention, chewing, lip closure, reflex swallow and ingestion, sitting position, manipulating of food on the plate, transport of food to the mouth, the opening of the mouth, manipulating food in the mouth, swallowing, energy, eating three-quarters of less of food, alertness, apparent eating time.

Interviews conducted alongside structured observations are a useful addition to assessments and allow for detection of several interrelated problems (Westergren 2006). Eating difficulties are hard to measure and therefore qualitative information can support understanding the intertwined problems and focus on more than the functional aspects of eating difficulties.

It is important to recognise the degree of impairment of eating difficulty will not necessarily correlate with the impact on eating disablement (Perry and McLaren 2003). For example, some participants in the interview study by Perry and McLaren (2003) who presented with severe difficulties on an eating disability scale described how these were either accommodated for or severely impacted on 'typical' eating arrangements. Finger foods may support people with eating disabilities after stroke to improve their oral intake; however, finger foods are not limited to this population and may be provided to promote oral intake in all people in hospital after a stroke.

1.5 Models describing eating difficulties in people after stroke

Models exist to help describe eating difficulties experienced after a stroke. Figure-1-1 presents a figure to show multiple factors which impact eating in people after stroke, focusing on a broader perspective than just swallowing. Figure-1-1 highlights observable eating difficulties following stroke such as cutting up food, controlling delivery of food to the mouth, low energy and remembering a mealtime but fails to provide a comprehensive representation of changes that occur as a result of stroke and impact on eating. Factors presented are limited to physical eating impairments that are observable. The figure omits wider sensory, cognitive, gustatory and mood effects factor that can impact on eating after a stroke.

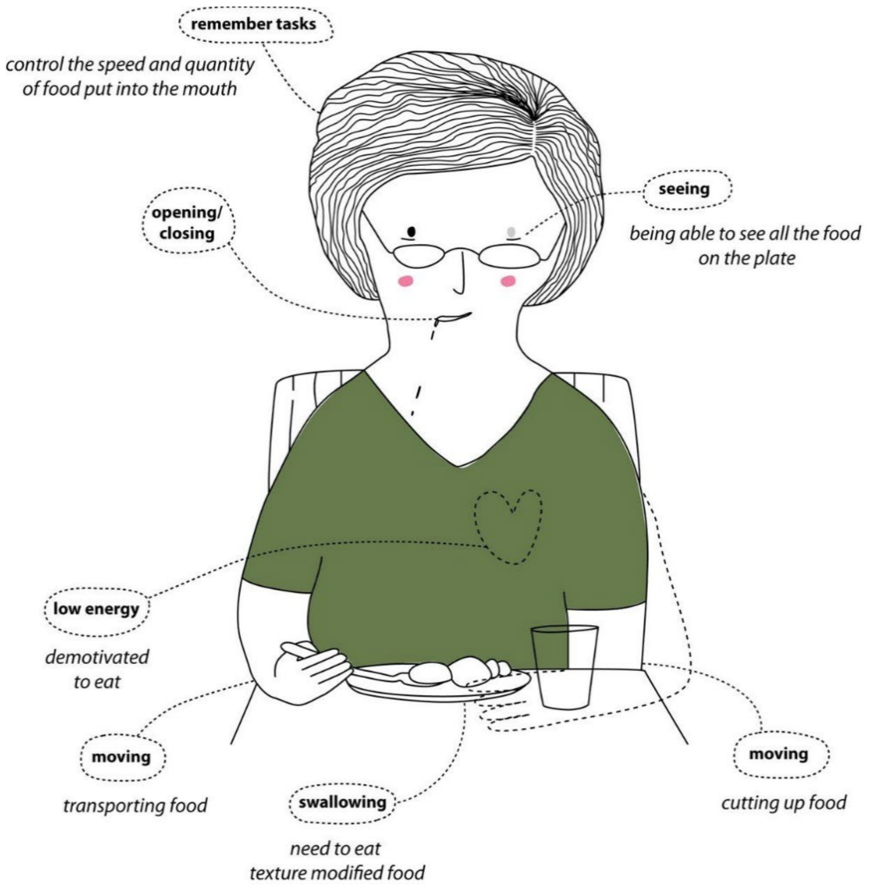


Figure-1-1 Eating difficulties in people after stroke based on Neves (2014)

By focusing on eating difficulties from a medical perspective, Figure-1-1 fails to represent the wide-ranging factors that impact on eating and on a person's mealtime experience. Viewing these difficulties from a single viewpoint and addressing difficulties focusing singularly on the physical disability of a person limits the applicability of using this model to fully understand this complex phenomenon. The omission of key factors demonstrates the need to consider all aspects of nutrition after stroke in the development of future interventions aimed at supporting nutritional intake in this group.

The multiple components that impact on eating after stroke are presented in a conceptual model by Klinke et al. (2013) shown in Figure 1-2. Klinke et al. (2013) describe 'eating difficulties' after stroke as an overarching concept, inclusive of several factors influencing a person's ability to consume food and enjoy eating. The model focuses on eating difficulties from the acute phase until six months post-stroke and, therefore, may not fully represent the factors experienced in the hospital specifically. It can be difficult to truly represent the reality and complexity of eating difficulties within a conceptual model (Klinke 2013). However, this model illustrates that eating difficulties can be impacted by physical, mental, social, and psychological challenges and attempts to provide a forum for holistic interventions to support patients to adapt to these difficulties with eating post-stroke.

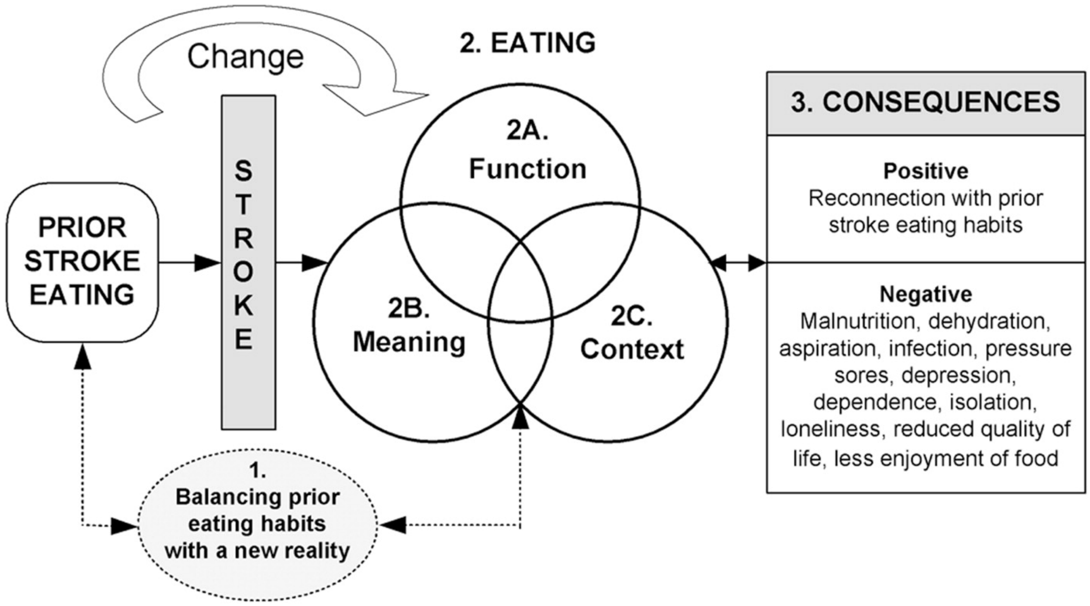


Figure 1-2 Conceptual model of eating difficulties following stroke (Klinke et al. 2013).

Reprinted from Disabil. Rehabil., 35(17), by Klinke ME, Wilson ME, Hafsteinsdóttir TB, Jónsdóttir H., title: Recognizing new perspectives in eating difficulties following stroke: a concept analysis, pages: 9, (2013), with permission from Taylor and Francis www.tandfonline.com.

The model by Klinke et al. (2013) is based upon a concept analysis from a review of quantitative and qualitative studies and suggests that eating after stroke is influenced by not only functional factors but also meaning and contextual factors. Function factors relate to the neurological deficits that impact on a person's eating difficulties, characterised by perceptual deficits, cognitive impairment, or lack of motor control. Meaning factors relate to the social factors of eating and a person's change in appearance, including embarrassment with diminished control. Contextual factors related to external factors that can impact eating, such as the ability to buy and prepare food, adverse effects of medication, poor oral hygiene, or ill-fitting dentures.

The production of the model aimed to provide health care professionals with a guide to assessment for helping stroke patients with eating difficulties (Klinke et al. 2013). It highlights the importance of systematically assessing eating difficulties, focusing on meaning, functional and contextual issues, all factors that might facilitate successful rehabilitation. The model highlights the multi-dimensional nature of eating difficulties associated with stroke and encourages considering the impact on the person, for example, reflecting the level of discomfort and satisfaction with eating. The interrelated components of meaning, functional and contextual factors show the importance of recognising all three components within the assessment and design of an intervention to support rehabilitation.

The final stage in the conceptual model by Klinke et al. (2013) identifies the consequences of changes to eating habits. These are mainly associated with negative consequences unless the person can reconnect with prior stroke eating habits. These consequences encompass far more than a change in nutritional status, noticing the challenges on an individual's physical, mental, social and psychological wellbeing. The model clearly shows that the stroke can cause a change in eating from prior eating habits and considers important factors to support an individual in their rehabilitation of eating after stroke. However, the model does not provide a clear idea of how it can be used to support changes in clinical practice or fully consider the context of a hospital environment. Therefore, additional models are considered.

1.6 Impact of eating difficulties on the person after a stroke

Swallowing and associated eating difficulties can extend further beyond the specific impairment and encompass aspects ranging from eating and nutrition, to social interactions and relationships and human functioning (Shune and Linville 2019). Dependency at mealtimes is associated with reduced quality of life, worse clinical outcomes and delayed recovery (Altman et al. 2010) and has broad implications in relation to the effects of eating difficulty and eating rehabilitation. People after a stroke who are dependent on support at mealtimes are commonly dependent on support for other activities of daily living (Westergren et al. 2002a) and more likely to be discharged to institutional care (Mauthe et al. 1996). Dependency with mealtime tasks has also been described as humiliating for some, with patients after stroke reported to be reluctant to ask for help with meals (Jacobsson et al. 2000).

The existence of eating difficulties is associated with a person being more dependent on activities of daily living (McLaren and Dickerson 2000) and therefore requiring an increased length of stay within rehabilitation (Finestone et al. 1996). It is well documented that inadequate nutrition can lead to poorer functional outcomes post rehabilitation and longer hospital stays (Finestone et al. 1996; Marshall et al. 2014; Nii et al. 2016).

Perry and McLaren (2003) pg. 366 described how the psychological responses of people after stroke ranged from "bewilderment, through dismay to despair" with eating difficulties impacting on social eating. Jacobsson et al. (2000) interview study of people after stroke in a neurological unit at the Northern Sweden University Hospital showed that patients after stroke described feelings of shame with regards to their changed appearance and the impact of this on their social eating. A loss of social eating activities has also been shown to detach patients from their social networks and cause isolation and loneliness (Klinke et al. 2013).

Qualitative studies focused on mealtimes in people after a stroke show that people are afraid of spilling food or swallowing incorrectly and that they can experience unpleasant feelings during mealtimes. The conceptual model by Medin et al. (2010) in Figure 1-3 attempts to further describe the impact of eating difficulties showing how people after a stroke are 'striving for control' during mealtimes and are conscious of attempting to eat safely and properly. A constant comparative analysis from interview transcripts with people after stroke revealed that people avoided situations in which they are unable to eat safely or properly due to embarrassment (Medin et al. 2010).

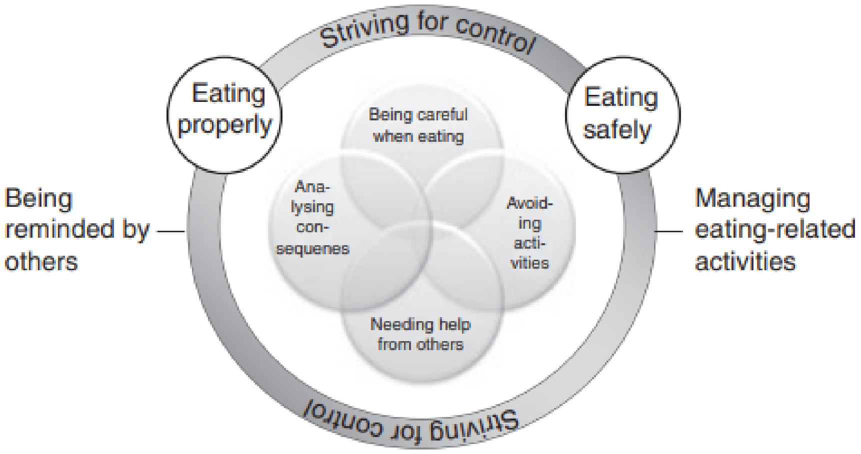


Figure 1-3 'Striving for control' with eating after stroke (Medin, 2010).

Reprinted from Scandinavian Journal of Caring Sciences, 24(4), by Kerstin Tham, Regina Wredling, Magnus Von Arbin, et al, title: Striving for control in eating situations after stroke, pages: 9, (2010), with permission from John Wiley and Sons.

The model conveys the complexities of eating difficulties for people after stroke, with strategies required to achieve control at the core. The model highlights the complex aspects of person-centred eating, but it does not consider the influence of the overarching context or environment in which the person may be placed. In addition, the model focuses on eating difficulties in stroke post three months, so not necessarily capturing the acute changes and impact of the hospital context.

1.7 The complexity of factors impacting on food intake

Additional layers of complexity for patient mealtimes exist within healthcare settings. National guidelines suggest people with disabilities after a stroke should receive rehabilitation in a dedicated stroke inpatient unit (NICE 2013). In this setting, it is important to ensure that nutritional intake during rehabilitation is optimal. However, interrelated and dynamic factors exacerbated by the 'healthcare system' can impact food intake and mealtime experience.

A conceptual model shown in Figure 1-4 by Keller et al. (2014) include the overarching environmental and government or 'system' factors when defining the complexity of factors impacting on food intake. Although this model was developed to explain influences on food intake in people with dementia in long term care settings, it can easily be transposed to relate to the multiple levels of influence for people after stroke within the hospital environment. Keller et al. (2014) model extends our understanding of the overarching influences relating to mealtimes in institutional care, including the individual's needs, the environment and - importantly - the influences of government on policy, guidelines and regulations. Within a hospital, budgets and institutional policies will influence levels below and therefore require full consideration.

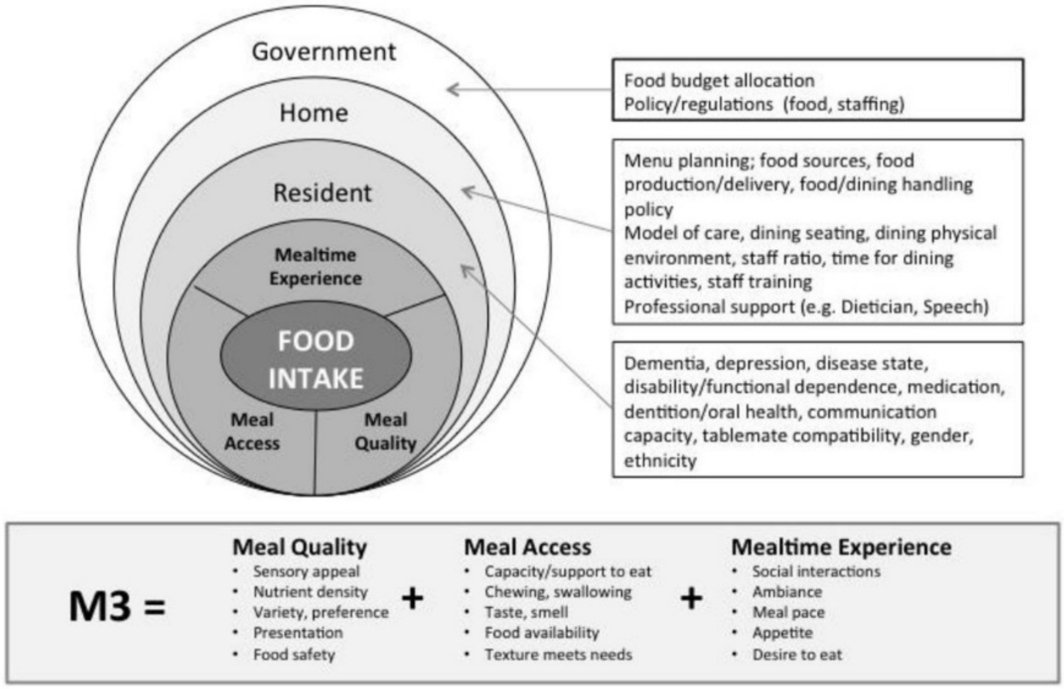


Figure 1-4 Mealtime intervention conceptual model (M3) (Keller et al. 2014)

Reprinted from Journal of the American Medical Directors Association, 15, by Heather Keller, Natalie Carrier, Lisa Duizer, Christina Lengyel, Susan Slaughter, Catriona Steele, title: Making the Most of Mealtimes (M3): Grounding Mealtime Interventions with a Conceptual Model, pages: 158-161, (2014), with permission from Elsevier.

Keller et al. (2014) describes the domains influencing food intake as meal experience, meal quality and meal access (M3). These domains described by Keller et al. (2014), link closely with the three domains (context, meaning and function) in the eating stage identified by Klinke et al. (2013). By describing the dynamic interplay between factors that impact eating and drinking experiences, Keller et al. (2014) and Klinke et al. (2013) both highlight the importance of not just focusing on the physical eating difficulties, but the influence on social factors or mealtime experience. Klinke et al. (2013) present negative consequences of eating difficulties after stroke as isolation, loneliness, depression, less enjoyment of food, and reduced quality of life as equal components. Inclusion of mealtime experience means that consequences move beyond the medical view of mealtimes in a hospital setting. Interventions to address food intake need to not only influence nutritional outcomes but also consider the mealtime as an experience and integral to social wellbeing and participation. Mealtimes are far more than an opportunity for nutritional intake and are integral to a person's identity and culture. Poor mealtime experiences can go beyond increasing the risks of undernutrition and can impact social aspects. Interventions should be designed to address multiple outcomes.

In contrast to models by Klinke et al. (2013) and Medin et al. (2010), the model by Keller et al. (2014) highlight factors relating to a person's background, such as gender and ethnicity, as influencing on a person's mealtime experience, meal access and meal quality. Belonging to an ethnic group can coincide with specific mealtime rituals, types of food chosen and preferred access to support. Ethnicity can be specific to the individual and emphasise that food intake can be influenced by individual factors. The ethnic background of a person can influence mealtime rituals, meal choices, acceptance of support, and eating position.

Klinke et al. (2013) refer to external factors that impact the provision of food as contextual factors, e.g., the ability to buy or prepare food but does not comment specifically on the environment or food quality. Conversely, from a wider system approach, the model by Keller et al. (2014) refers to support available from staff or visitors as part of the meal access domain, which can affect a person's mealtime experience. Keller et al. (2014) extend thinking to consider how the meal quality such as presentation, nutritional density and texture of the meal as an important influence on food intake. These are important considerations particularly in a healthcare setting where foodservice factors influence the quality of the food provided.

The models relating to a stroke-specific population focuses on people adapting to new stroke behaviours by moving towards pre-stroke eating habits (Klinke et al. 2013) and shows individuals strive for self-control with their eating (Medin et al. 2010). Conversely, these factors are not considered in the model by Keller et al. (2014) developed for people with dementia. This may be due to the population the model is based on. People with dementia can often be dependent on activities of daily living including eating (Holmes and Berry 2008) and can experience physical eating difficulties including challenges transferring food from the plate to the mouth (Watson 1993) and cognitive deficits for example not recognising cutlery (McNamara and Kennedy 2001).

These challenges relate to those seen in people after stroke, however, people after stroke find themselves with new disabilities based upon an acute event, whereas for people with dementia these changes can progress overtime and therefore aiming to achieve 'pre dementia' eating habits are less viable.

Models by Medin et al. (2010) and Klinke et al. (2013) exist to describe eating difficulties in people after stroke. However the model by Keller et al. (2014) considers the multiple interrelated components of a hospital mealtime and factors that impact on food intake. This model is used to further describe the interrelated components within a hospital mealtime in Chapter 3.

1.8 Key NHS guidelines to prevent undernutrition

Keller et al. (2014) model describes the government as having an overarching influence on food intake. Independent and NHS Health and social care services in England - e.g., care homes, nursing homes and hospitals - are independently regulated by the Care Quality Commission (CQC), which aims to ensure that services provide 'safe, effective, compassionate and high-quality care' (Care Quality Commission 2021). The CQC states that the NHS is responsible for providing adequate food, drink and appropriate support to meet the nutrition and hydration needs of any person during an overnight stay in hospital (Care Quality Commission 2017). Ensuring that patients receive adequate nutrition is consistently high on the NHS agenda and hospital food guidelines and policies are reviewed regularly (NHS England 2015; Forsey 2018).

1.8.1 NHS hospital food standards

Recent initiatives to improve nutrition and hydration care in healthcare services have been provided by the UK Government, which considers the provision of appropriate food to be vital to the prevention and treatment of malnutrition (British Dietetic Association 2017). In August 2019, the UK government announced a new review of hospital meals to improve the food quality and provide national standards that fit with the Public Health England's *Eatwell Guide* (Department of Health and Social Care 2019). Recommendations to support a system-level change to improve hospital food provision were published in 2020. These included each hospital implementing a food and drink steering group of relevant professionals, complying with the highest standards of food safety and reporting on food sustainability and waste (Shelley 2020).

Each NHS hospital in England must also comply with the five key hospital food standards (Department of Health 2014) which remain current and legally binding. These include maintaining a food and drink strategy to support the nutrition and hydration of patients, healthy eating for the whole community including staff and sustainable procurement of catering services. Three standards specifically focus on nutrition and hydration of patients in hospital:

- Use of a validated nutrition tool to monitor for risks of malnutrition
- Examples of operationalising improved nutrition and hydration care
- An evidence-based resource for healthcare professionals and caterers to help the prevention and treatment of malnutrition in care settings (British Dietetic Association 2017).

The five hospital food standards aim to encourage commissioners to acknowledge the importance of hospital food for the health and wellbeing of patients, to supplement their medical treatment, and aim to decrease healthcare costs (Department of Health 2014). Local commissioners are responsible for exercising these guidelines in line with national priorities for funding (NICE 2017) (Sustain 2017). It is estimated that by abiding by the standards set out by the Department of Health (2014), NHS Trusts could make monetary savings as well as savings such as reduced length of stay and improvements in catering efficiency.

1.8.2 National guidelines for nutritional management after stroke

Further guidance exists to support specific patient groups at risk of undernutrition in hospitals. The National Institute for Health and Care Excellence (NICE) compiles regular updates of the best available evidence to support best practices within the UK healthcare system (NICE 2014). NICE guidelines for supporting nutrition and hydration in people after acute stroke, updated in 2019, focus on timely assessment of swallow function, consideration of oral nutritional supplements, specialist dietary advice and/or tube feeding for those at risk of malnutrition (National Institute for Health and Care Excellence (NICE) 2013). They highlight that best practice to support adequate nutrition should be rooted in person-centred care, considering patients' beliefs and decisions at the centre.

Despite this recognition that adequate dietary intake can improve outcomes for people at risk of malnutrition, finding the safest and most effective methods for providing it is a complex matter (National Institute for Health and Clinical Excellence 2006). At present, despite a high prevalence of eating difficulties in people after stroke, there is a lack of evidence-based nutritional interventions to support food intake, with nutritional support not provided in a coordinated or recognised holistic approach in hospitals (Perry et al. 2013).

1.8.3 Menu planning guidelines for finger foods in NHS hospitals

The CQC regulation 14 for meeting nutritional and hydration needs states: ‘People's food must be placed within their reach and presented in a way that is easy to eat, such as liquidised or finger foods where appropriate’ (Care Quality Commission 2017 para. 4). This guidance applies to all providers registered with the CQC, including hospitals, care homes and hospices.

The British Dietetic Association (2017) provide menu planning guidelines for setting up a finger food menu in hospitals. The guidance supports offering finger food choices that can be eaten easily, using the hands as opposed to cutlery to improve dietary intake and suggests the use of finger foods can be used as a type of ‘therapeutic diet’ offered as a separate àl la carte menu. Therapeutic diets are diets in which the nutrition e.g., protein and fat, can be manipulated to support specific patient groups (British Dietetic Association 2017). This is documented in the standards for hospital food set by the (Department of Health 2014). The guidelines provide some practical guidance for implementation but no specific evidence to suggest their effectiveness (British Dietetic Association 2017).

Hospitals’ performance against these guidelines are evaluated through Patient-Led Assessments of the Care Environment (PLACE) assessments. Organisations are audited against their provision of finger foods for patients unable to use cutlery, asking ‘Can patients choose a complete meal option that can be eaten without cutlery (finger food)?’. An audit of dementia care by the Royal College of Psychiatrists and completed by 195 hospitals in England and Wales hospitals showed that 75% of hospitals had access to alternative complete meal options that can be eaten without cutlery, up from 65% in 2016 to 2017 (Royal College of Psychiatrists 2019). This meant that one in four hospitals still did not provide a finger food meal option and therefore scope for improvement remains.

1.9 An introduction to finger food

Finger foods are defined as foods presented in a form that are easily picked up with the hands and transferred to the mouth; without the need for cutlery (Department of Health 2014; Buckinghamshire Health Care NHS Trust 2015). Typically, finger food menus include small sandwiches, pieces of quiche, cut up vegetables and cake slices or foods made as individual or bite sized portions. They are provided for people managing to eat regular textured foods

‘Finger foods’ is the most commonly used term within the literature, however, additional terms include ‘utensil less diet’ or ‘dementia diet’ (Ford 1996) and ‘hand-held’ foods (Young et al. 2005).

Alternative definitions of finger food in the literature appear to depend on the client group and how they are implemented (Malerba et al. 2015). Cluskey and Kim (2001) define finger foods as foods that hold their shape. Ford (1996) includes liquid items in a cup as finger food as a utensil is not required. Pouyet et al. (2014) designed finger foods shaped from a purée consistency designed for people with oral phase dysphagia and difficulty with chewing.

1.9.1 Who are finger foods recommended for?

For people after stroke or with cognitive impairment, finger foods can be used to support participation at mealtimes (Volkert et al. 2015; British Dietetic Association 2017; Volkert et al. 2019). The Social Care Institute for Excellence (2009) recommends using finger foods to enable independence and to prevent loss of dignity and embarrassment when eating in front of others as spills are minimised (Barratt et al. 2001).

Finger foods are recommended for people who prefer to eat smaller meals, little and often (The Patients Association 2016) or who fatigue quickly during a larger meal. Family carers are reported to use finger foods at home for their relatives with dementia, who experience reduced appetite and decrease in physical status (Ball et al. 2015).

1.9.2 What are the proposed benefits of finger food?

The main reported benefits of using finger foods are enhancement of nutritional intake and maintenance of weight (Soltesz and Dayton 1995). The increased sensory interaction with food, through touch, has the potential to improve the amount of food eaten (McCrickerd and Forde 2016). Finger foods have potential to reduce behavioural problems during mealtimes, as people are preserving their ability to eat for themselves, creating a more enjoyable experience (Godart et al. 2017).

Finger foods are also described as a more flexible approach to dining (Burbidge 2013). They can be used as a portable alternative to a plated meal and can be eaten or available on the go (Crawley and Hocking 2011). They can be served variously at a table, for example in place of a meal, as snacks for between meals or supplied in different locations to be accessed throughout the day (Airedale NHS Trust 2015).

1.9.3 Examples of finger foods in practice

Reports of hospital settings introducing finger food menus are documented in media reports (Buckinghamshire Health Care NHS Trust 2015; BBC 2017; The Shrewsbury and Telford Hospital

NHS Trust 2017; Ford 2018). These reports provide anecdotal evidence which are descriptive in nature. Hospital Trusts have implemented the use of finger foods as multimodal approaches to nutritional intervention without successfully showing that they singularly have a positive impact on patients (James et al. 2017). Buckinghamshire Health Care NHS Trust (2015), for example, implemented finger foods alongside blue crockery to help patients with dementia to recognise foods; however, no study results have been published.

Finger foods are recommended for use in care homes (Crawley and Hocking 2011) and information presented by the Alzheimer's society for carers encourages the use of finger foods as a mealtime intervention in the home. They suggest cutting food into bite size pieces to make it easier for people to consume (Alzheimer's Association 2017).

1.9.4 Potential barriers to using finger foods

The inconsistency in resources provided by catering contracts in care settings across England causes variability in the availability of finger foods and to whom they are offered (Department of Health 2014). The reasons behind this are likely to be based upon funding available for food provision and professional consensus of those working in the institution.

Prejudices and expressions of family members or professionals act as potential barriers to providing finger foods in care settings (Godart et al. 2017). Godart et al. (2017) suggest that family members or professionals may view eating with the fingers a regression of independence and returning to 'child-like' behaviours. Indeed, eating has more complex implications than simply providing nutritional intake (Bisogni et al. 2007). It is important to consider food and eating practices, attitudes, and beliefs as a significant part of cultural identity. Food choices have emotive and cultural connotations and 'traditional' mealtimes can vary according to socioeconomic status, geographical location and ethnicity (Amella and Aselage 2012). These traditions, etiquettes and behaviours can influence the acceptability of eating foods with the hands.

Additional barriers relating to the provision of finger foods in care settings relate to the context. Godart et al. (2017) recommend that additional hygiene measures are required when using finger foods. There are also specific challenges in maintaining food at an adequate and safe temperature to eat, which create further barriers to their use.

1.10 What are the gaps in current knowledge?

Currently, there is no research that demonstrate true effectiveness for finger foods and recommendations are simply based on professional consensus (British Dietetic Association 2017; The Shrewsbury and Telford Hospital NHS Trust 2017; Volkert et al. 2019). Most recommendations and guidelines regarding the use of finger foods focus on supporting people with dementia, not people after stroke, who also have a high incidence of eating difficulties.

Volkert et al. (2015); British Dietetic Association (2017); Volkert et al. (2019) and The Social Care Institute for Excellence (2009) recommend using finger foods in order to improve access to food and enhance people's independence during mealtimes. However, the variation in the provision of finger foods across health and social care settings and the complexity of factors involved in mealtimes means in-depth research to fully understand the use of finger foods in care settings is warranted.

1.11 Chapter conclusion and thesis plan

This introductory chapter has highlighted the longstanding issue and high prevalence of undernutrition in NHS hospitals. Poor nutrition in hospitals impacts clinical, social and psychological outcomes for patients, leading to longer hospital stays, poorer functional outcomes and social isolation. The chapter draws attention to people after stroke being one patient group frequently at risk of undernutrition and reduced oral intake, and who experience negative associated physical, social and psychological consequences. Promoting oral nutritional intake of hospital food for people after stroke in hospital is important to support rehabilitation. However, the complexity of the multiple interrelated influences of both patient factors such as eating difficulties and dysphagia, and system factors means that hospital mealtimes can be considered complex and appropriate interventions to support oral intake are difficult to evaluate.

At present, there is very little knowledge regarding the use of finger food (food that can be eaten without cutlery) in terms of practicality and nutritional content. There are groups of people, such as people after stroke, who may benefit from the use of finger foods to support nutritional intake, dignity, and control over hospital mealtimes. Nutritional guidelines which recommend the use of finger foods do not specifically focus on people after stroke as a group who would potentially benefit from the intervention. However, finger foods may promote oral nutritional intake of hospital food in this population.

There is anecdotal evidence that some hospitals in the UK offer finger food menus; however, this varies across NHS Trusts. Further understanding of the published literature is required to understand what we know about finger foods in care settings and where the gaps in the knowledge lie. The following chapter presents a systematic search of the existing empirical research looking at the use of finger foods in care settings, with the remaining thesis focused on a feasibility study based on recommendations from the review.

Chapter 2 **Reviewing the literature**

2.1 Introduction

Chapter two presents an integrative review to identify and summarise the current literature on the use of finger foods in care settings. The chapter builds upon an integrative review published by the candidate (Heelan et al. 2019). The published paper focused on findings from published empirical research studies relating to the use of finger foods in care settings, searched up until October 2018. The paper identified knowledge gaps in the related evidence to the use of finger foods in hospitals and suggested that the use of finger foods may increase nutritional intake and enhance independence and well-being for adults with cognitive impairment in long-term care settings. However, the studies included did not provide enough robust evidence, with regards to study design and reporting, for the effectiveness of these types of foods in care settings and to justify fully introducing finger foods.

This chapter adds an up-to-date search, which found two additional published studies reported since publication of the integrative review paper. This chapter additionally includes a systematic and thorough search of the grey literature.

The aims of the literature review are to:

- To locate and synthesise empirical literature on the use of finger foods for adults in care settings
- Identify key considerations for implementing a finger food menu in care settings for adults
- Recognise gaps in current literature and recommendations for future research.

2.2 Approach to literature review

This review takes the form of an integrative review; a review typically used in healthcare research and evidence-based practice to inform decisions regarding clinical care (Whittemore and Knafl 2005). Integrative reviews use a systematic and detailed search strategy followed by objective critique, summary and inferences to fully understand a subject area (Souza et al. 2010; Noble and Smith 2018). Evidence is collected and collated from both experimental and non-experimental designs including quantitative and qualitative data (Whittemore and Knafl 2005; Noble and Smith 2018).

An integrative review method was selected over a traditional systematic review method. This is because the included papers were not ‘gold standard’ randomised control trials and had varied methodologies which restricted meta-analysis. This limited the ability to combine the results of experimental or randomised control trials and gather evidence to answer a specific research question relating to intervention effectiveness, as per a systematic review (Noble and Smith 2018).

Inclusion of grey literature in this review supported the finding of a larger body of evidence regarding the use of finger foods, and provided additional context - including practical approaches regarding the use of finger foods - which may not be addressed in the academic literature (Adams et al. 2017). Grey literature is defined as documents produced at multiple levels, including government, academia, business and industry, in print and electronic formats but not controlled by commercial publishers (Public Health England 2019a). Grey literature is an important part of addressing the evidence base in complex interventions to consider a wide literature search (Simkhada et al. 2004); however, evaluating source quality is paramount.

2.3 Materials and methods

The methods involved in combining data with a range of designs can be complex and therefore a rigorous approach should be used to ensure transparency. The methods for this integrative review follow the five steps outlined by Souza et al. (2010):

1. Definition of the guiding question
2. A detailed and systematic search of the literature
3. Data extraction
4. Critical analysis of included publications
5. Interpretation and synthesis of results.

Reporting is based upon the PRISMA checklist to ensure rigour in the reporting mechanisms (Moher et al. 2009) shown in Appendix A.

2.3.1 Selection criteria

Eligibility criteria focused the review and provided relevant information to define the research question (Aveyard, 2010). Scoping searches of the topic identified a paucity of literature; therefore, eligibility criteria were broadened. This allowed identification of as many relevant articles as possible. Eligible studies were determined by pre-defined criteria based upon the PICOST tool (Population, Intervention, Comparator, Outcomes, Setting, Type) (Aveyard 2010), presented in Table 2-1.

Table 2-1 PICOST: Eligibility criteria

Category	Criteria
Population	Adults, 18 years or over
Intervention	Any use of a finger food menu including an increase in finger foods offered or complete change of the menu.
Comparator	Studies included if any comparator present, or none at all.
Outcome	Any subsequent outcomes.
Setting	Any institutional setting (e.g., long-term care centres, assisted living residence, residential homes, nursing homes, hospital, medical ward)
Type	All types of empirical research

2.3.2 Search strategy

Pre-defined searched terms, generated with support from a medical librarian, were used to search databases. Search terms were combined with Boolean operators (And/Or/Near) and MeSH (Medical Subject Heading) terms to retrieve the widest scope of papers possible. Pre-defined search terms included: adult, patient, elderly, senior, geriatric, dementia, Alzheimer's, neurocognitive impairment, stroke, neurocognitive decline, finger food, buffet, utensil less, menu modification, mealtime intervention, dementia diet and eating with hands or fingers. Searches were initially conducted in October 2018 and then re-ran in December 2020. Full search terms are listed in Appendix B.

The following databases were searched using pre-defined search terms:

- MEDLINE (to December 2020)
- EMBASE (to December 2020)
- CINAHL Plus® with Full Text (1937 to 2020)
- PsycInfo (1880 to 2020)
- Web of Science Core Collection (to December 2020)
- Cochrane Library (to December 2020)
- AMED (to December 2020)

All databases were searched using the EBSCO platform except EMBASE, which used the OVID platform. No language restrictions were in place with any searches. At full text screening, any texts not available in the English language were excluded. Reference lists of included papers were searched.

To search the grey literature, sources from an index recommended by Public Health England (2019a) were searched using term ‘finger food’ in May 2020. Sources included British library, King’s fund, MedNar, OpenGrey and TRIP. Appendix C lists resources searched by date, search terms used, and records obtained.

The main author and another experienced investigator screened all titles and abstracts initially. Full texts, regarded as relevant, were sourced, and considered for inclusion by the main author and members of supervisory team.

2.3.3 Data extraction and quality

To ensure familiarity with the text, included papers were read several times. To extract relevant data, a pre-prepared and piloted instrument based on the data extraction table by Souza et al. (2010) was used. This allowed for easy comparison across data sources and served as the initial point to seeing patterns and relationships for further interpretation (Whittemore and Knafl 2005). A separate template was used to extract relevant information from the grey literature.

Evaluating the quality of primary sources in an integrative review is challenging due to the wide range of methodologies used (Whittemore and Knafl 2005). It is difficult to find a validated tool to be able to directly compare studies of different methodological stance. Katrak et al. (2004) conducted a systematic review that identified 121 different tools for critical appraisal. It concluded that no one tool was regarded as the gold standard and that the researcher should cautiously select the most appropriate tools for appraisal.

Studies, including grey literature sources, were appraised using the most fitting Critical Appraisal Skills Programme (CASP) tool for the study design (CASP 2017). The CASP tool enabled a systematic evaluation of studies, considering validity, credibility, relevance, and results of papers. Findings from the CASP tool (CASP 2017) were discussed and agreed with the supervisory team. None of the studies attained all the criteria assessed by the CASP appraisal form. However, assessing whether the studies omitted key components or simply did not report them was not feasible, despite attempts to contact the authors.

Information from quality assessment should be considered within the data synthesis to form conclusions (Popay et al. 2006); however, evaluating the quality of primary studies with diverse research designs is complex (Whittemore and Knafl 2005). Within the meta-synthesis, increased weight of evidence was given to published peer-reviewed studies, which were used to generate themes within the narrative synthesis and to summarise findings. As per guidelines from Whittemore and Knafl (2005), grey literature contributed less to the analytic process due to concerns that this literature lacked rigour. The majority of peer reviewed studies included in this review were low in quality (further discussed in section 2.4.2); therefore, assigning weight to individual peer-reviewed studies within the analysis process would have little effect on the results. All peer-reviewed studies were included in the analysis with comments relating to study quality included in the discussion section. Due to the limited amount of research available on this topic, all studies were included in the data synthesis regardless of quality. The purpose of the critical appraisal was not to exclude studies based on quality but to emphasise the quality of evidence that was available.

2.3.4 Data synthesis

The reporting of clinically diverse outcomes and using studies at high risk of bias (Higgins and Green 2011) meant that meta-analysis (the merging of quantitative results from numerous studies) was not appropriate (Bowling 2014). Peer reviewed and grey literature sources were coded, before being categorised and synthesised systematically in line with guidelines by Whittemore and Knafl (2005) for preparing an integrative review. Codes were generated inductively from publications. Line by line coding was used to extract data from primary sources to simplify and sort data into manageable data forms. Next, these descriptive codes were displayed in a visual matrix to observe patterns and themes. Codes were compared and contrasted and analysed iteratively by grouping descriptive codes into overarching themes. These overarching themes were discussed and agreed with the supervisory team. Relevant studies were included in the thematic analysis regardless of quality.

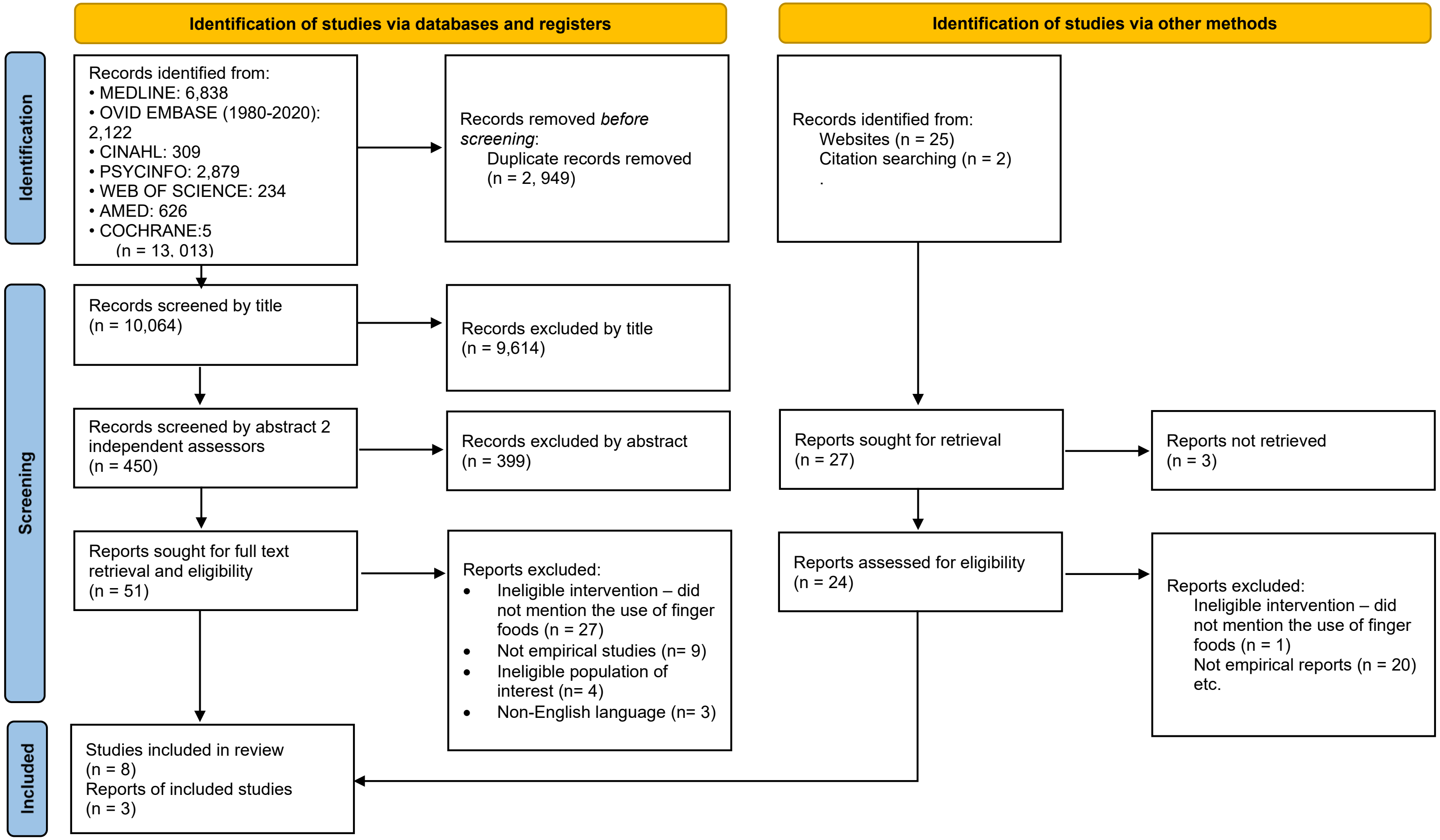
2.4 Results

2.4.1 Descriptive findings

Eight empirical peer-reviewed publications and three grey literature sources were included in the final selection. Figure 2-1 summarises the selection process using the PRISMA (Preferred Reporting items for Systematic Review and Meta-analysis) flow diagram and includes reasons for exclusion. One clinical study listed on a database for registering clinical studies around the world (clinicaltrials.gov) could not be included as no associated results have been published (Moreau and Verbrugghe 2017).

Table 2-2 provides a summary of the characteristics for peer-reviewed studies. Studies were carried out in long term care settings in the USA (Nangeroni and Pierce 1985; Jean 1997), the UK (Soltesz and Dayton 1995; Ford 1996; Barratt et al. 2001), France (Pouyet et al. 2014), the Netherlands (Visscher et al. 2020) and Japan (Kimura et al. 2019). The design of studies varied including observational studies (Nangeroni and Pierce 1985; Ford 1996; Pouyet et al. 2014), a pilot study (Jean 1997), a case study (Barratt et al. 2001), a retrospective study (Soltesz and Dayton 1995) and most recent publication of a feasibility study (Visscher et al. 2020). No peer-reviewed studies included a randomised sample. Sample sizes were generally small, ranging from six participants (Barratt et al. 2001) to 114 (Pouyet et al. 2014). All participants had a diagnosis of dementia or other psychiatric condition. Participants presented with a range of eating difficulties, which were attributed to their cognitive impairment. These included difficulties using utensils (Nangeroni and Pierce 1985; Soltesz and Dayton 1995; Ford 1996; Jean 1997; Barratt et al. 2001); e.g., poor hand or finger control, tremor and limited concentration or high level of distractibility (Nangeroni and Pierce 1985). All studies used a variety of outcome measures.

Table 2-3 provides a summary of characteristics from grey literature sources. Grey literature sources reported studies undertaken in the USA (Bailey 2007; Gilboy et al. 2019) and the Netherlands (Tuinier et al. 2014), with one source describing the use of finger foods in an acute care setting (Bailey 2007). Publications included one conference proceeding (Tuinier et al. 2014), and two dissertations (Bailey 2007; Gilboy et al. 2019). Designs of studies which had not undergone peer review varied, with one reporting randomisation (Bailey 2007), however, full details of how this was conducted were not provided. The paper by Tuinier et al. (2014) was the only paper to evaluate patient experience and evaluated relative and staff experience of using finger food with survey or written feedback. Grey literature sources showed finger foods trialled with a more diverse range of participants including patients with traumatic head injury (Bailey 2007).



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

Figure 2-1 PRISMA flow diagram.

Table 2-2 Summary of publication characteristics from empirical studies

Author (Year)	**Study design**	**Setting**	**Population (Number)**	**Intervention**	**Comparator**	**Outcomes**	**Assessment method**	**Results**
Barratt et al. (2001)	Single case methodology	Specialist care ward, UK	Females with dementia (6)	Finger food menu	Standard menu	• Wellbeing • Independence • Weight • Costs	Observations with dementia care mapping (DCM) Change in weight	• 50% of participants maintained weight, 33% gained weight, 17% lost weight. Mean weight gain of 0.4kg with finger food menu. • DCM scores showed 100% of participants increased levels of independence and wellbeing with finger food menu. • £1 increase in food costs per patient per week.
Ford (1996)	Observational study	Behavioural health unit, UK	Psychiatric patients (10)	Finger food menu, five small meals per day.	No comparator	• Food intake • Weight • Quality of Life (QOL) • Self esteem	Observation methods (not fully described) Assessment of abnormal involuntary movement	• 70% of participants increased food intake and gained weight. • Mealtimes reported to be more enjoyable for 100% participants, families and staff. • Quality of life and self-esteem increased by helping patients gain some independence.

Author (Year)	**Study design**	**Setting**	**Population (Number)**	**Intervention**	**Comparator**	**Outcomes**	**Assessment method**	**Results**
Jean (1997)	Pilot study	2 nursing and rehabilitation homes, USA	6 with Alzheimer's Disease; 6 without Alzheimer's Disease (12)	Finger food menu	Standard menu	• Weight • Food intake • Independent feeding skills	Percentage of food eaten (0%, 25%, 50%, 75%, 100%) Scale to measure feeding dependence (dependent feeding, hand over hand cueing, independent with tray set up, total independence)	• 83% of participants maintained or gained weight, 17% continued to lose weight post finger food menu introduction, • 100% participants increased percentage of food eaten. • 100% participants became more independent with feeding skills. • 25% participants no longer required high calorie and protein supplements, suggesting cost savings.
Kimura et al (2019)	Observational study	Nursing Home, Tokyo, Japan	Residents with dementia (21)	A finger snack with sauce	A finger snack without sauce	• Participant choice	Staff questionnaire	• Snack consumption was greater for the with-sauce options than for the without-sauce.
Nangeroni and Pierce (1985)	Observational study	Intermediate care unit for psychogeriatric patients, USA	Psychogeriatric patients (22),	Soft textured finger foods added to menu.	No control	• Independence with feeding • Quality of life	Not described	• Nil numerical results displayed. • Generally positive responses and increased palatability with finger foods. • Participants enjoyed wider variety of food. • Less eating assistance required.

Author (Year)	Study design	Setting	Population (Number)	Intervention	Comparator	Outcomes	Assessment method	Results
Pouyet et al. (2014)	Observational study	8 Nursing homes, France	Residents with AD (114)	Puree finger food, with and without sauce, 1 or 2 layers and 2 different shapes.	Puree finger food with different presentations	• Participant choice	Staff questionnaire	• No conclusions regarding effectiveness of finger food. • 92% participants trialled finger foods, suggesting well accepted. • Finger foods with sauce and visual contrast chosen first. • Shape of finger food was not shown to exert an influence on food attractiveness but were relatively easy to pick up, appealing and attractive for the subjects who participated in this study.
Soltesz and Dayton (1995)	Retrospective study	Alzheimer's care centre facility, USA	Residents with AD (54)	Increased number of finger foods on solid food menu for 6 months	Purée diet	• Weight • Mean food intake for breakfast, lunch and dinner calculated from % consumed	Mean weight over one month for each resident % of meal consumed recorded in medical chart	• No significant change in weight for control and intervention group. • Significant increase ($p<0.05$) in food consumption overall and for some meals with intervention • Anecdotal report that 'generally cost no more money', staff, retraining or food purchase.

Author (Year)	Study design	Setting	Population (Number)	Intervention	Comparator	Outcomes	Assessment method	Results
Visscher, A. (2020)	Feasibility study	Nursing home, Netherlands	Residents with dementia (15)	Fruit and vegetable finger foods offered as additional snacks		• Dose received • Fidelity • Appreciation	Researcher completed 3-day food record charts Staff and carer feedback from	• Fruit and vegetable consumption were significantly higher • The consumption of finger foods did not lead to significant caloric compensation during the main meals • Some caregivers presented the finger foods with a fork which was not in accordance with the serving protocol. • 7/12 members of staff indicated positive experiences using finger food. 5/12 members of staff indicated mixed reaction to finger foods, indicating challenges with textures of food provided and advice for improved implementation in the future. • Residents accepted finger foods, despite staff concerns finger food would be unfamiliar to residents.

Table 2-3 Summary of characteristics from grey literature

Author (Year)	Source type	Setting	Population (Number)	Purpose of source	Relevant outcomes	Assessment method	Findings
Bailey (2007)	Masters project dissertation	Intensive care unit, USA	Males with Traumatic Brain Injury, 18-68 years old (5)	Pilot study to evaluate use of finger foods for patients after TBI	• Food intake	• Nurse completed food record charts	• No significant difference in amount consumed between standard and finger food meals. • Consistent amount of finger food consumed across the day, as opposed to standard meal, where less consumed for dinner • Insufficient calories eaten across both standard menu and finger food
Gilboy et al (2019)	Masters project dissertation	60 bed Residential home, USA	Adults with dementia	Develop a finger food menu for residential home	• Nil outcomes reported	• No assessment	• Menu designed with head chef and dietitian. • Finger foods not appropriate for residents on pureed diet. • Regular foods modified into finger foods; soup served in a mug. • Foods served with sauce in a separate cup, not overcooked.

Author (Year)	Source type	Setting	Population (Number)	Purpose of source	Relevant outcomes	Assessment method	Findings
Tuinier, K et al. (2016)	Conference proceeding	Nursing home, Netherlands	Residents with dementia (5)	Observational and survey research evaluating the experience of residents, relatives and caregivers with finger food	• Experience of relatives and caregivers' • Food intake • Meal duration	• Likert scale questionnaire • Mealtime observations	• Mean dietary intake: 239g of regular meal when being fed by a nurse; 195g of an independent eaten finger food meal. • Mean time for meal duration: 26 minutes to eat standard meal; 27 minutes for finger food meal. • Patients received less help with eating finger foods • 60% of relatives and 94% of caregivers had a positive opinion about finger food. • 50% percent relatives and 88% caregivers reported finger food positively influenced independency of patients.

2.4.2 Quality assessment

Quality assessment using the Critical Appraisal Skills Programme (CASP) tool for each included publication are presented in Appendix D. The CASP tool was chosen for the following reasons: i) checklists are available for both case-control and qualitative research papers; ii) each tool covers validity, results, and clinical relevance.

Results indicated that two publications reporting quantitative findings were of low quality (Soltesz and Dayton 1995; Jean 1997). Soltesz and Dayton (1995) used unmatched control and intervention groups with respect to key characteristics. The control group included 11 residents consuming a modified purée diet, and an intervention group of 43 residents with no swallowing difficulties eating a regular textured diet. Additionally, confidence intervals were not provided for key outcomes, providing no indication of variability (Soltesz and Dayton 1995). In the studies by Jean (1997) and Visscher et al. (2020), a pre–post study design was used where participants acted as their own control groups. Confounding factors were not reported, making it difficult to attribute maintenance or increase in weight and increase in intake to the finger food menu intervention (Jean 1997; Visscher et al. 2020) . In addition, Jean (1997) offered results using only descriptive statistics, which causes difficulties making generalisations about the results and puts external validity at risk. Based on the CASP case control checklist, the study by Pouyet et al. (2014) and Kimura et al. (2019) satisfied most of the CASP criteria, although external validity was limited considering the attractiveness of pureed finger foods has not been widely reported.

Studies using a qualitative methodology were considered low quality (Nangeroni and Pierce 1985; Ford 1996; Barratt et al. 2001). Ford (1996) did not report sufficient detail of the study methodology or clear statements of findings relating back to research aims. The studies by Nangeroni and Pierce (1985); Barratt et al. (2001) did not sufficiently consider the participant and researcher relationship, or ethical factors, and reported unclear statements connected to findings and credibility. Due to the low quality of studies identified by the CASP critical appraisal tool, it was not possible to make conclusions regarding the effectiveness of finger foods in care settings. The review aimed to summarise considerations for implementing a finger food menu in care settings and recognise gaps in current literature and recommendations for future research.

Grey literature sources were difficult to assess due to the limited information provided. Studies were unable to satisfy questions from CASP on the results sections, where underpowered studies with very small sample sizes were reported, or studies which have not published results with appropriate outcome measures.

2.4.3 Meta synthesis

Four main themes were generated inductively through thematic analysis:

- Finger food menu implementation
- Importance of a team approach
- Effect on nutrition
- Influence on wellbeing.

2.4.3.1 Finger food menu implementation

The specific implementation of the finger food menu varied across studies. Studies included in this review showed finger foods being used as a substitution for a standard menu (Jean 1997; Barratt et al. 2001; Bailey 2007; Gilboy et al. 2019), served in addition to the standard menu (Nangeroni and Pierce 1985; Soltesz and Dayton 1995) and served as snacks throughout the day (Ford 1996; Kimura et al. 2019; Visscher et al. 2020).

Most studies described finger foods as foods that did not require cutlery (Soltesz and Dayton 1995; Ford 1996; Pouyet et al. 2014; Gilboy et al. 2019) or could be eaten with the hands (Nangeroni and Pierce 1985; Barratt et al. 2001; Pouyet et al. 2014). Generally, finger foods were appropriate for residents eating regular textured diets and those with no symptoms of oro-pharyngeal dysphagia (Bailey 2007). However Nangeroni and Pierce (1985); Barratt et al. (2001); Pouyet et al. (2014) trialled using softer foods and purée forms of finger food for older adults who may have difficulties chewing or dysphagia. Pouyet et al. (2014) reported overall that purée finger foods were well accepted by adults with Alzheimer's disease and that shape did not influence food attractiveness, but it was deemed important to support manipulation with the hands.

There was limited explanation of the design and development phase of the finger food menus in each of the included studies, however, menu recommendations and reasons for them differed.

- Jean (1997) reported the importance of initially implementing a simple menu, emphasising that many foods on the standard menu were foods naturally eaten with the hands.
- Gilboy et al. (2019) suggested the design of the finger food menu was based on foods already served at the home to ensure residents did not feel segregated and to utilize food already purchased.
- Jean (1997); Gilboy et al. (2019) included hot cereal and soup in a mug as finger food as cutlery was not required to consume the food.

- Barratt et al. (2001) found that some finger foods, such as roast potatoes and malt loaf, were too difficult to eat, and therefore were not offered on the menu throughout the study period. Additionally, jacket potatoes, initially not deemed appropriate as finger food, proved to be popular and convenient.
- Kimura et al. (2019) found finger foods provided with sauce were preferred by participants in the study.
- Gilboy et al. (2019) recommended that sauce was provided separately in a pot to support manipulation with the hands.
- Staff feedback from the study by Visscher et al. (2020) expressed the importance of providing appropriately textured finger foods that residents were able to eat independently.

The expenditure required to implement a finger food menu was considered by Soltesz and Dayton (1995); Jean (1997); Barratt et al. (2001). However, no studies reported a robust economic evaluation, consequently leading to conflicting results. Soltesz and Dayton (1995) suggested that finger food menu implementation did not cost any more money than the provision of standard foods. Jean (1997) suggested that protein and high energy supplements were discontinued in 25% of participants trialling a finger food menu, giving a cost saving. Conversely, in a later study, Barratt et al. (2001) reported an increase in monetary cost per person to implement the finger food menu.

Studies included in this review did not provide specific details about how a finger food menu was developed or the approaches or strategies that ensured successful implementation in a care setting. Studies make no reference to implementation science described as ‘the scientific study of methods to promote the uptake of research findings into routine healthcare in clinical, organizational, or policy contexts’ (BMC Implementation Science 2021). Gilboy et al. (2019) and Visscher et al. (2020) allude to tailoring the intervention to fit the routine and procedures already existing in the setting as a strategy that promoted the success of the finger food menu. For example, Gilboy et al. (2019) designed the finger food menu using options that were already provided on the standard food menu and Visscher et al. (2020) served finger foods at times already dedicated to meals. Having experienced clinical and support staff (Barratt et al. 2001) or implementing the menu in a ‘skilled nursing facility’ (Gilboy et al. 2019) impacted the successful implementation of the finger food menu intervention, however further details about what strategies supported success or why were not reported.

2.4.3.2 **Importance of a team approach**

A common theme arising in three published studies was the desirability of collaboration between clinical and catering teams to support the provision of a finger food menu (Soltesz and Dayton 1995; Jean 1997; Barratt et al. 2001). Despite catering services often being seen as nonclinical services, their involvement meant that food was presented in a way that patients could access and provided for observable changes in clinical outcomes (Barratt et al. 2001). The importance of a team approach to implement a finger food menu in a residential home was also discussed by Gilboy et al. (2019); Visscher et al. (2020). In these studies, caregivers were also viewed as part of the team as their 'attitude to serving' was observed to influence acceptability of finger foods to residents. The attitude and behaviours of staff were reported as important to be 'interested' (Jean 1997; Barratt et al. 2001) and 'committed' (Barratt et al. 2001) to supporting the project. Visscher et al. (2020) recommended future studies that supported teamwork by conducting a 'tasting session' with residents and staff before the project commenced to establish which foods would be best accepted and would be easy to prepare by staff.

Agreement between budget holders (typically clinical managers, commissioning services and catering teams) is required to justify the need for finger foods, particularly in studies that showed increased costs for providing finger foods (Barratt et al. 2001). Training staff to understand the need and rationale for using finger foods was one approach influencing the maintenance and success of implementing the intervention across departments (Ford 1996; Jean 1997).

Soltesz and Dayton (1995); Barratt et al. (2001) described collating feedback from the catering and clinical teams to assist with the development and implementation of the finger food; however, limited detail was reported regarding how data were collected, and the changes made.

2.4.3.3 **Effect on nutrition**

Nutritional outcomes were measured in three published studies through assessment of food intake using food chart reviews, plate waste observations and changes in weight (Soltesz and Dayton 1995; Ford 1996; Jean 1997). Unpublished studies focused on nutritional intake, including macro and micronutrients as a main outcome (Bailey 2007).

Maintenance of weight and increased food intake during the finger food menu intervention period were reported in three published studies (Soltesz and Dayton 1995; Ford 1996; Jean 1997). A full description of the intervention was not provided, and nutritional values of food eaten were not detailed. Therefore, despite increased food intake, nutritional intake could not be evaluated. In contrast, unpublished studies by Bailey (2007); Tuinier et al. (2014) suggested that nutritional intake did not increase during the finger food menu intervention, and participants ate more when fed directly by nursing staff (Tuinier et al. 2014). Bailey (2007) reported that participants were more likely to maintain food intake throughout the day with finger foods, as opposed to the standard menu where participants ate less during dinner meals. Ford (1996) suggested that changes in nutritional status could affect medical status; however, an explanation regarding how medical status will change was not included.

2.4.3.4 **Influence on wellbeing**

The fourth theme describes improvement in well-being reported in all published studies during the implementation of finger foods. Well-being was measured formally by Barratt et al. (2001) using dementia care mapping. Barratt et al. (2001) showed an increase in the mean well-being scores of residents who were offered a finger food menu, which was maintained at a six week follow up period. However, the pre–post study design and small sample size used by Barratt et al. (2001) limit the control of confounding variables in the complex long-term care setting and makes it challenging to attribute these findings wholly to the food offered.

Improvement with eating independently for people choosing to eat finger foods was reported in four studies (Nangeroni and Pierce 1985; Jean 1997; Barratt et al. 2001; Tuinier et al. 2014), despite variations in the outcome measures used. Observations from mealtimes demonstrated an increase in the mean percentage of observations recorded as ‘independent feeding’ over lunchtime meals (Barratt et al. 2001). Contrastingly, Jean (1997) created a scale that showed three of twelve residents became fully independent eating their meal when offered finger foods, despite being entirely dependent with feeding during the baseline measure of a ‘standard meal’. Nangeroni and Pierce (1985) did not provide details of how independence was measured. Considering that the reflexive views of the researcher were not described, the risk of bias is increased making it difficult to determine whether or not this would lead to a reduced requirement for support by staff and visitors (Barratt et al. 2001).

The paper by Tuinier et al. (2014) was the only included paper that focused on the experience of relatives and caregivers. Questionnaire results showed differences in the way relatives and caregivers perceived finger foods and whether they positively influenced independence with eating. In this study, 60% of relatives had a positive opinion on the use of finger foods, compared to 94% of caregivers.

2.5 Discussion

The purpose of this integrative review was to locate and synthesise empirical literature (published and grey literature) on the use of finger foods for adults in care settings, to inform future research and to support clinical practice and policy decisions. The lack of high-quality trials identified from the systematic search implies that the use of finger foods for adults is yet to be robustly evaluated.

Despite guidelines proposing the use finger foods to support people after stroke (British Dietetic Association 2017), all published empirical studies focused on people with cognitive impairment or dementia. This emphasises the gap in understanding regarding the use of finger foods for people after stroke and reinforces the need for research to investigate whether this group of people would benefit from them.

This review demonstrated some evidence of improvement in relevant outcomes, such as food intake, with the use of finger foods. However, this was demonstrated in studies that lacked a control, which creates difficulties in ascertaining the cause of the effect shown. In contrast to these results, there was evidence in unpublished studies which suggested that dietary intake did not necessarily increase when fingers foods were offered. There appears to be some evidence of improved wellbeing when using finger foods with people with cognitive impairment, however, outcome measures vary or have limited validity. The variation in implementation of interventions provided across these publications provides additional challenges when comparing outcomes. On the other hand, this does emphasise the need for a pragmatic approach to future research, considering all the stakeholders involved and acknowledging mealtime interventions as complex.

One considered strategy shown across studies in this review is the use of a ‘team approach’ or collaboration through the multidisciplinary team of nursing staff, dietetics, catering teams to promote successful use of the menu within the context. Studies commented on gaining support, interest and commitment of staff involved, including incorporating feedback for continuous improvements (Soltesz and Dayton 1995). Across studies, reports lacked detail regarding how the motivation, values, or beliefs of professionals, caregivers, or catering teams were influenced during the rollout of the menu. The review did not highlight which strategies would effectively support collaboration between a multidisciplinary team.

Teamwork is essential to promoting dietary intake in healthcare, due to the multiple aetiologies of reduced oral intake and risks of malnutrition. Engagement with teams to support implementation of new practice has been reported elsewhere in the literature. Conchin and Carey (2018) suggest that engagement with a team of staff will optimise the implementation of a hospital mealtime intervention and describes the following strategies to optimise staff engagement:

- Incorporate staff in the research process, such as via qualitative methods
- Increase staff knowledge and promoting active participation in nutritional care

- Provide joint leaders for research projects such as researchers from a university background partnering with clinicians
- Ensure active communication through regular communication of results
- Increase staff knowledge and education in the form of in-services, workshops, education sessions or attendance at ward meetings by researchers.

These strategies may increase the time scale required for a project and intensify the workload for researchers. However, the intervention must have the best chance of being integrated into clinical practice. Staff involvement with organisational change is also recognised as a determinant of sustainability for embedding new practices into routine care. The NHS Institute for Innovation and Improvement Sustainability Model proposes factors likely to affect sustainability (Doyle et al. 2013). Factors relating to staff include frontline staff awareness and involvement in organisational changes, and the commitment of clinical and organization leaders are essential for sustainability (Doyle et al. 2013). The sustainability of interventions is important to ensure that an intervention becomes part of an organisational routine and limits variability in outcomes over a prolonged period. Within large-scale intervention trials, evaluation of the strategies to support the maintenance of an intervention should be reported.

The studies included in this review do not explicitly discuss strategies that support the implementation of a finger food menu in care settings. Studies focused on what the finger food menu comprised and on the delivery methods. The lack of detail and theoretical underpinning of implementation strategies leads to difficulties considering how a similar finger food menu may be implemented in a different context, such as a hospital, and reduces the translation of research findings into practice.

Addressing the problem of inadequate dietary intake in care settings is complex. Poor nutritional status can be due to multiple interrelating factors related to disease, aging, psychosocial factors, and system factors which include the lack of responsibility or prioritisation for nutrition care (Young 2015). The complexity and unpredictable nature of mealtime interventions make it difficult to provide solutions to the problem of inadequate oral intake and risks of malnutrition; therefore, the design and implementation of a new intervention need to account for this complexity (Young 2015).

There have been strong arguments for the use of implementation science to address the risks of inadequate oral intake in hospitals and care settings (Young 2015). The overarching aims of theoretical approaches to implementation science are to i) understand how or why implementation succeeds or fails, ii) guide the translation process of research to practice and iii) assess or evaluate implementation (Nilsen 2015). There is an increased interest in the use of theories, models, and frameworks to systematically integrate results to understand the mechanisms to implementation success (Nilsen and Bernhardsson 2019). Understanding the mechanisms to implementation success is important for research to support nutritional intake in hospitals as it enables implementers to design or tailor strategies to fit the local context and stakeholders involved. This ultimately supports implementation effectiveness and research that can be translated into practice, deemed essential for investment in research.

Conchin and Carey (2018) acknowledged that the translation of results from research studies into practice is challenging and complex. Conchin and Carey (2018) used a modified Delphi study to explore the barriers and enablers to effective mealtime interventions from professionals involved in a diverse range of mealtime interventions in the acute care setting. Content and thematic analysis of responses from experts identified steps deemed essential for implementing a hospital mealtime intervention were presented as a framework for developing mealtime interventions. Although this framework was devised by experts in Australia, it could be transferred to an international audience who experience similar rates of malnutrition and challenges with mealtime practices (Conchin and Carey 2018).

While the framework was developed without specific reference to implementation science, Conchin and Carey (2018) reported that concepts from the Promoting Action on Research Implementation in Health Services (PARIHS) framework emerged. The PARIHS framework describes evidence, context, and facilitation as supporting implementation success (Harvey and Kitson 2015a). ‘Evidence’ was described in the framework by Conchin and Carey (2018) as the need to determine baseline evidence and acknowledgement of implementation barriers to the specific hospital or ward. The PARIHS construct of ‘Context’ related to the framework by Conchin and Carey (2018) as gaining executive support and considering organisational culture and engagement of staff, patients, and visitors and the PARIHS construct of ‘facilitation’ related to the framework as considering a project lead and strategies to foster resilience within the project team. The PARIHS framework concepts could be useful in identifying and understanding strategies that support the implementation of a finger food menu.

A study by Cluskey and Kim (2001) undertaken in the USA has shown that finger foods are judged by healthcare professionals, working in long-term care settings, as being beneficial for residents, cheap and easily implemented in institutions. In addition, the assumed limited adverse effects and expense means that recommendations for using finger foods continues to be detailed in clinical guidelines on nutrition and hydration in geriatrics (Volkert et al. 2019).

None of the studies identified in this integrative review reported a clearly described economic evaluation to assess the benefits of using finger foods as an intervention and to evaluate the best use of available resources alongside highest patient satisfaction (Brent 2004). When implementing a change in practice, it is important to reflect the true direct and indirect costs of healthcare interventions (McMahon and Sin 2013). The limited cost evaluation in nutritional studies has been documented elsewhere (Moick et al. 2019).

Ford (1996) acknowledged the potential of using a finger food menu to support older adults with a wide range of eating difficulties, including mental health or physical difficulties. An increase in food intake in people with cognitive impairment has been shown in other studies with different presentations of food. In a crossover, randomised controlled trial undertaken in a nursing home, Young et al. (2005) demonstrated an increased energy intake when high carbohydrate foods were offered in place of a usual meal, which was not fully described. Although that study did not aim to evaluate the use of finger foods, it was noted that many of the high carbohydrate foods could be defined as finger foods, such as bread with jam, hard-boiled egg, muffins and slices of cheese. In addition, a greater severity of cognitive deficit and atypical motor behaviour was associated with greater intervention success (Young et al. 2005). Young et al. (2005) acknowledged that, in this trial, people with nutritionally controlled diabetes were excluded. This highlights that suitability for a finger food diet would need to be assessed individually because the nutritional content and presentation may not meet some people’s dietary needs.

Bailey (2007) evaluated the use finger foods for patients with traumatic brain injury (TBI) aged 18 to 68 years old during their stay in intensive care. The sample population was unique from other studies identified, as participants were considerably younger in age with eating difficulties resulting from TBI as opposed to a progressive cognitive impairment. The small sample size was recognised by the authors as a limitation to this study (Bailey 2007), with recruitment difficulties secondary to strict eligibility criteria including only patients eating a regular textured diet.

Interestingly, none of the studies in this review fully explored the experiences of staff, carers or the recipient of the finger foods, despite indications that they may have positive benefits on wellbeing and quality of life. These less tangible and quantifiable outcomes are however considered important to measure (Conchin and Carey 2018) to support effective and efficient service delivery and likely impact on the primary outcome (Collins et al. 2017a). The included conference abstract, with no associated published paper, used a survey methodology to explore the views of residents, caregivers and relatives regarding providing a finger food menu in a nursing home (Tuinier et al. 2014). In the future, more in-depth research investigating the experience of residents, caregivers and relatives could give additional information on the acceptability of this menu (Tuinier et al. 2014) to support effective and efficient service delivery (Collins et al. 2017a).

The findings of this integrative review complement findings from broader reviews on interventions to improve dietary intake. Malerba et al. (2015); Abdelhamid et al. (2016) reported positive outcomes regarding the use of finger foods, despite highlighting the need for further high-quality investigations and well-powered randomised control trials. The review by Abdelhamid et al. (2016) focused on interventions to support food intake in people with dementia, including two studies that classified the use of finger foods as a direct dietary intervention included in this integrative review (Soltesz and Dayton 1995; Jean 1997). A focused search on the use of multiple dietary interventions meant that the review did not specifically address the use of finger foods and limited the range of publications found. The descriptive review by Malerba et al. (2015), in France, discussed the use of finger foods for people with dementia in community and home settings. Malerba et al. (2015) suggest valuable outcomes relating to the use of finger foods, for example, a reduced carer workload, increased independence and individualised care for people with dementia. Although useful results were reported, the review did not show a systematic approach to searching the literature or provide a quality critique of the publications included.

2.6 Strengths and limitations

This integrative review incorporated a range of study designs, in addition to the synthesis of quantitative, qualitative and unpublished data. This combines additional levels of complexity which can introduce bias (Whittemore and Knafl 2005). To certify the high quality of this review, rigorous systematic approaches were used throughout. Two reviewers screened abstracts for inclusion, and discrepancies were dealt with through discussion to reduce bias. The full texts were chosen following discussion with the other investigating authors. Caution was taken when acknowledging grey literature sources, however, overall, this range of literature adds to the full understanding of the question. The finding of a clinical trial with no associated results by Moreau and Verbrugghe (2017) could suggest either that publishing of trial results may not be a priority for the researchers, or that there is evidence of publication bias and authors were unable to publish results. The content of this review did not report strategies to support implementation of a finger food menu in care settings. This limits the ability to use the results of the review to support the uptake of the findings into routine care and translate findings into practice.

2.7 Recommendations for future research

This review presented evidence that suggests using finger foods in health care settings could improve relevant outcomes, such as food intake and wellbeing. However, further high-quality investigations and well-powered randomised control trials which control for bias are required to evaluate the true effectiveness of the intervention. Based upon the results from this integrative review, gaps in current knowledge from published and unpublished research were revealed.

The following key recommendations for future research should be considered.

1. Provision of finger foods for people after stroke as the population of interest.

Considering that the research available focused on people with dementia or cognitive impairment, the extent to which these results can be transferred to people after stroke is unknown. Both people with dementia and people after stroke can present with similar eating difficulties (Chang and Roberts 2008) e.g., difficulty with recognising food and utensils (Lee and Song 2015), reduced concentration, attention and memory to plan executive functions such as eating and swallowing impairments (Liu et al. 2019). However, there is a stark contrast between the sudden onset of these challenges for people experiencing acute stroke compared to the gradual decline of these skills in people with cognitive impairment. In addition, the physical impairments that people after stroke experience may mean that the use of foods that do not require cutlery are more appropriate for them. Guidelines recommend the use of finger foods for people after stroke; however, at present this is not reflected in the research available.

2. Adequate sample sizes and consideration of setting.

Data to support adequate power and sample size calculations are required to ensure that in a future trial a difference between groups can be determined. Consideration of challenges carrying out research in acute care settings should be regarded utilising the complex interventions framework (Craig et al. 2008).

3. Consideration of study design using a mixed methods approach.

A mealtime in healthcare settings must be considered a complex intervention due to the multiple interrelated components (Craig et al. 2008). None of the studies in the review considered using finger foods within care settings as a complex intervention. It is important to design a study that can fully evaluate the complex intervention and build the evidence base to understand the strategies that promote successful implementation of a finger food menu in a hospital setting. The MRC complex interventions guidelines recommend a mixed method, phased approach, with a preliminary study to address key uncertainties prior to the full evaluation (Medical Research Council 2006). A mixed methods approach can provide both quantitative and qualitative data to refine the intervention processes, support continuing adaptation of intervention and evaluate the study design in preparation for a full trial (O'Cathain et al. 2015). Quantitative research methods can measure the intervention and the implementation outcomes while qualitative methods can be used to understand the processes that facilitate adoption of an intervention. Both components are important to determine the success of the intervention and provide a better understanding of the research issues than either approach alone (Palinkas et al. 2011). Because implementation research occurs within a real-world context, participants experiences, and perceptions of the intervention are key to determining the success or failure and should be considered. Qualitative methods through interviews can provide the opportunity for participants to elaborate on their experiences and voice their opinion regarding the intervention. Observations can provide the opportunity to view how the intervention is working within the context.

4. Full description of finger food menu intervention that can be replicated.

Herke et al. (2018) suggest using a template for intervention description, such as the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al. 2014), for all studies describing interventions to promote dietary intake. It is important to design an intervention that is informed by implementation science principles to increase the likelihood of success of the intervention within the context. To account for variations in implementation, careful consideration to the context and engaging executive support and staff involvement should be used (Conchin and Carey 2018).

5. Outcome measures that include use of validated tools, with full considerations of costs

Validated tools to support higher methodological rigor and validation of measures should be used to ensure accurate results that can be generalizable. The findings from this review highlight the need for a full economic evaluation to justify the implementation of the intervention.

2.8 How the results of the review informed the future study

This review located and synthesised empirical literature on finger foods for adults in care settings. The included studies focused on people with dementia or cognitive impairment and showed a gap in our understanding about using finger foods for people after stroke. It showed no current existing evidence that evaluates whether using a finger food menu in hospitals effectively increases food intake for people after stroke. The findings of this review were used inform the intervention development phase of this next study to develop a finger food menu for people in hospital after a stroke and subsequently supported the design of a preliminary study to evaluate the feasibility and acceptability of using the menu.

A literature review can clarify whether the targeted intervention is effective for the specific population, identify facilitators and barriers to using the intervention in a specific context, and identify uncertainties for using the intervention (O'Cathain et al. 2019a). As part of the intervention development phase, the MRC complex intervention framework suggests completing a systematic literature review to identify the relevant and existing evidence base (Craig et al. 2008). The MRC framework suggests that results from a literature review can support understanding the components of the intervention, mode of delivery, and intensity to make sense of varying outcomes (Craig et al. 2008).

The studies included in this review variably described the components of a finger food menu, offering only brief descriptions of the types of foods provided. The studies included in the review suggested that finger foods were commonly offered to patients who did not have dysphagia but did show examples of puree or soft finger foods. The studies did provide examples of finger food menu items and information on how these were chosen. For example, studies reported using standard foods already purchased and repurposing them as finger food, providing a simple menu of limited options, and using similar foods to those already served to ensure that participants did not feel segregated. The review showed that the specific mode of delivery of a finger food menu varied across studies and contexts, with nil recommendations made as to which mode of delivery was most effective. For example, serving times varied from offering finger foods as snacks across the day to replacement meals. The review did not report on strategies to support implementation but highlighted the importance of a team approach to develop the menu to fit the context it was being served.

To design a finger food menu for use on the stroke rehabilitation ward, input from stakeholders such as patient and public involvement representatives, including those with experience of being on a stroke rehabilitation ward, clinical and catering staff, was considered. This enabled a menu to be designed to fit the context of the stroke rehabilitation ward and ensured food items were available and could be served. In addition to this, to capture the views and experience of the whole team involved in mealtimes on the hospital ward, the future study incorporated interviews with members of staff, both clinical and catering. This provided the opportunity for the menu to be developed and adapted based on the experiences of those involved in its delivery.

The design of a future preliminary study to address the feasibility and acceptability of using a finger food menu was based on the design of previous studies. The summary of publication characteristics table (Table 2-2) provided an overview of outcomes relating to nutrition and wellbeing and examples of how these were measured to evaluate the use of finger foods in care settings. Nutrition outcomes were measured through food chart reviews, plate waste observations, and weight changes. The only study based in a hospital setting by Bailey (2007) used food intake as the primary outcome, measured through nurse-completed food record charts. The studies in this review did not use robust methods to evaluate the views or experiences of people in the hospital. The paper by Tuinier et al. (2014) was the only study to comment on the experience of relatives and caregivers, but uncertainty remained regarding the best methods to collect this data. Information was reported on costs to implement a finger food menu, but these were not robustly measured.

Food intake measures and measures of nutritional status as outcome measures resonated with other studies to evaluate the effectiveness of nutritional interventions for people with dementia (Herke et al. 2018). The most appropriate outcomes for evaluating the use of a finger food menu for people after a stroke remained uncertain. In addition, the best study design to evaluate the use of a finger food menu in a hospital, whether there will be a willing population to take part, and whether the intervention could be implemented and accepted in a hospital setting remained uncertain. The preliminary feasibility study addressed these uncertainties before a full evaluation and implementation of the intervention would be considered.

2.9 Chapter conclusion and research question

The findings from this integrative review suggest that using finger foods for adults with cognitive impairment in long-term care settings may increase nutritional intake and enhance independence and wellbeing. However, the studies included do not provide robust evidence for the effectiveness of using these types of foods in care settings. Therefore, the results should be interpreted with caution. A limitation of the review was that the studies included did not report strategies that supported the implementation of a finger food menu within care settings, and therefore this remained an uncertainty for the intervention development stage. Studies focus on reporting what the finger food menu comprised and how it was delivered, without discussing or considering the strategies that promoted successful implementation. There appears to be a paucity of research for the use of this menu in hospital settings, despite UK nutritional guidelines recommending their use. This thesis recommends that further research to establish the effectiveness of using finger foods in hospital is conducted using a robust study design.

Studies found in this review had limited detail of the interventions used, varied in their use of outcome measures and lacked robust study designs e.g., the use of randomised control trials. This causes initial questions as to whether a randomised control trial could be conducted to evaluate the effectiveness of finger foods and whether this would be an appropriate approach. Bowen et al. (2009) suggest that conducting a feasibility study is of benefit where there are limited studies and lack of in-depth research on a topic. Before proceeding to a large multicentred randomised control trial, a study is required to establish the feasibility, acceptability and implementation cost of using a finger food menu. This will inform important parameters for a future trial.

Despite much of the literature in this review focusing on people with people with cognitive impairment as a result of dementia, this thesis has highlighted that people after stroke in hospital are one group at high risk of eating difficulties (associated with physical and cognitive impairments) and reduced food intake. Considering the potential benefits for patients with cognitive impairment highlighted in this review, people after stroke are a patient group who would potentially benefit from the use of finger foods and are a patient group in which this intervention has not yet been fully explored. A study to evaluate the use of finger foods for people after stroke in hospital would therefore provide a novel contribution to the current evidence base. The remainder of this thesis will present the systematic approach to establish the feasibility, acceptability and implementation cost of using a finger food menu with people after stroke to inform important parameters for a future randomised control trial

The following chapter provides an overview and methodology of the feasibility study presented in this thesis, including specific details regarding the development of the finger food intervention for use on a stroke rehabilitation ward in an NHS hospital in the South of England.

Chapter 3 Overview of intervention development and rationale for feasibility study

3.1 Introduction

Chapter three outlines the PhD candidate's approach to the study proposed in the previous chapter. It outlines the candidate's position as a Clinical Doctoral Research Fellow and the impact of this on the study. The chapter focuses on stages of development and design of the finger food menu, the intervention used in the study. The menu development was informed by evidence from the integrative review presented in Chapter 2 (Heelan et al. 2019) and a pragmatic, systematic approach to development, following guidelines from the Medical Research Council (MRC) on evaluating complex interventions (Craig et al. 2008). Subsequently, the definition of a feasibility study with rationale for its use, leading onto study aim and objectives using a mixed methods approach is described.

3.2 Approach to the study as a clinical - academic researcher

The PhD candidate approached this study as a Clinical Doctoral Research Fellow (CDRF). Being on a funded CDRF scheme enabled the candidate to maintain professional status and develop clinical skills as a registered Speech and Language Therapist (SLT) whilst embarking on the doctoral level research. The simultaneous, interrelated roles ('clinical academic role') facilitated transfer of knowledge across the 'theory-practice gap' (University of Southampton 2020). This meant that knowledge gained as a clinician supported the development of a clinically relevant and pragmatic research study and allowed research results to be translated straight into clinical practice.

As an SLT, the PhD candidate has specialist skills in assessment and management of adults with acquired speech, language and swallowing difficulties (dysphagia) in hospital. She worked as a specialist SLT on the stroke rehabilitation ward, the ward used for the study, from September 2016 to September 2018 and again post the data collection period for this study. This provided first-hand experience of working with people after stroke who experienced a sudden onset of eating difficulties and dysphagia.

Primarily, to members of staff in the hospital setting, the PhD candidate was identified as a registered SLT and subsequently a researcher. The PhD candidate could be considered an 'insider' due to being an established member of staff on the study ward (Asselin 2003). However, by not providing a clinical service to patients participating in the study and working elsewhere during the data collection and analysis period, she also gained an 'outsider' perspective. This proposed a balance between the 'insider' and 'outsider' perspective throughout the research study (DeWalt and DeWalt 2011). The research literature aims to weigh up advantages and disadvantages to the insider/outsider perspective. Bonner and Tolhurst (2002) suggest the advantages of the insider perspective are that the researcher is seen as a member of the group and is familiar with local conditions, culture and jargon, making it easier to gain acceptance, trust, and cooperation with a project. In contrast, disadvantages to the insider perspective are that the researcher may be biased towards findings or interpretations and experience role conflicts. Bonner and Tolhurst (2002) suggest that the advantages of the outsider perspective are that researchers are seen as objective observers and can see properties lost to the insider because of familiarisation. In contrast, disadvantages to the outsider perspective are that it may take the researcher a longer time to establish trust. In addition, linguistic jargon may desensitise the researcher to a group's needs or meanings, and the researchers may experience a culture shock that may delay or interfere with research.

The insider perspective meant that the PhD candidate was quickly accepted into the research setting and had trust and co-operation from other staff working in the area, which supported the study setup, study design, and allowed potential study obstacles to be accounted for within the protocol. Being seen as a member of staff may have impacted interview responses received from others of the same group and being familiar with the setting may have meant that routine clinical tasks were missed during observations. From an insider perspective, there was a requirement for the PhD candidate to consider bias towards findings or interpretations and to consider how to ensure these were objective, using reflexive memos.

As an outsider, the PhD candidate was not aware of the communication needs of patients approached for the study, and therefore, building rapport with patients and preparing resources to support communication impairments took longer. Further reflections on the insider-outsider perspective of the researcher are presented in Appendix E.

3.2.1 World views of the pragmatist researcher

As a clinical academic, the PhD candidate employed a realist view of science with a pragmatic viewpoint (Shannon-Baker 2016). The pragmatic viewpoint supported full understanding of the research problem (Shannon-Baker 2016), and focused on the 'why' and 'how' of the research in a real-life context (Robson and McCartan 2016). The research objectives of this project were designed to address key uncertainties highlighted from both grey literature and published literature knowledge regarding how a finger food menu was used on a hospital ward, what it should comprise and how should it be evaluated. The feasibility study presented in this thesis looked to answer ‘how’ the intervention was provided and whether it was acceptable to staff and patients.

Pragmatic researchers work to collect data practically in the clinical setting (Creswell and Plano Clark 2018), focusing on generating an action in contrast to philosophising (Robson and McCartan 2016). The pragmatic viewpoint aligns with the Economic and Social Research Council (2018) view, which advocates that all research should impact society. Pragmatism helped inform the design of the study and data collection methods, which attempted to remove the line between everyday life and research and aimed to embed inquiry into practical everyday situations (Morgan 2014). For example, this feasibility study evaluated the use of a finger food menu on a hospital ward, as opposed to evaluating the use of finger foods in a clinical lab environment. This meant that the multiple interrelated factors impacting on a hospital mealtime (further discussed in section 3.3.1) existed within the study and that factors relating to implementation could be explored. Being a ‘real world’ study with data collected in the clinical setting meant that the study design was carefully considered. For example, the limitations of using only one study ward and they layout and design of the ward meant it was not possible to incorporate randomisation of participants at an individual or cluster level, due to the high risk of contamination.

The pragmatic viewpoint is a contemporary viewpoint, only becoming accepted by researchers as a separate orientation during the 20th century (Teddlie and Tashakkori 2009). It is acknowledged as the third viewpoint after positivist and constructionist and aims towards a midpoint between the two (Robson and McCartan 2016). For pragmatists, knowledge is both constructed and based on experience and reality. Ontologically, pragmatists believe there are both singular and multiple realities (Creswell and Plano Clark 2018). Multiple realities focus on the idea that there may be more than one point of view required to gain a full understanding of the research phenomenon. A pragmatic viewpoint supports the use of multiple, qualitative and quantitative data collection and analysis procedures, based on the research question and seen as the optimal world view for mixed methods research (Creswell and Plano Clark 2018). It is important that the values of the researchers are considered within the interpretation of results (Teddlie and Tashakkori 2009). This project aimed to explore the diverse experiences of both members of staff working on the ward and patients included in the project, and therefore the design of the study incorporated interviews with both groups alongside observation to fully understand the complex organisational processes.

3.3 Complexity of a hospital mealtime

From a pragmatic viewpoint, the PhD candidate acknowledged that the real world is complex and contains different layers of social reality including the individual, group, institutional and societal levels (Robson and McCartan 2016). Planning and evaluating an intervention to address the components involved in eating and drinking for people after stroke in hospital is recognised as a complex process. Craig et al. (2008) describe a complex process as a process with several interacting components within a complex system.

3.3.1 Overview of interrelated components within a hospital mealtime

Within a 'hospital mealtime', complexity arises from both the interrelated components within food service and health care systems and the patient variability (Ottrey et al. 2018). Food service systems and health care systems have multiple demands from governmental and policy guidelines. They exist within a constantly changing environment beset with demands to face challenges caused by workforce turnover, adoption of technology, and adaption to meet service user demands (Ottrey et al. 2018). This feasibility study recognised complexity as variability in the patients' need for assistance with meal access, unexpected staff workflow interruptions to attend to hospital emergencies, and bed moves impacting on meal delivery. These occurred alongside direct physical, motor, perceptual, emotional and psychosocial difficulties impacting on eating and drinking as a result of neurological impairments caused by a person's stroke.

The complexity of factors impacting food intake are considered in the conceptual model by Keller et al. (2014), described in section 1.7. The model by Keller et al. (2014) explicitly refers to influences on food intake for people with dementia in long term care. These components can be transposed to highlight the complexity and interrelated components within a hospital setting, considering the health care system, e.g., hospital system, foodservice system and patient variability. Based on the conceptual model by Keller et al. (2014), Table 3-1 presents an overview of interrelated components within a hospital mealtime.

Table 3-1 Overview of interrelated components within a hospital mealtime

	Components
Hospital system	• Government and policy regulations relating to food and staffing including NHS guidelines and hospital food standards. • Food budget allocation. • Model of care including dining seating, physical dining environment, staff ratio, time for dining activities, staff training, professional support. • Hospital layout, bed management and flow
Food service system	• Government and policy regulations relating to food and staffing including NHS guidelines and hospital food standards. • Menu planning including food sources, food production, food delivery, food dining/handling policy. • Meal quality including sensory appeal, nutrient density, variety, presentation, food presentation, safety.
Patient variability	• Patient factors including disease state, depression, disability/functional dependence, medication, dentition, oral health, communication capacity, gender, ethnicity, food preferences, expectations of mealtimes. • Meal access including capacity and support to eat, chewing and swallowing ability, taste, smell, texture meets needs, food availability. • Meal experience including social interactions, meal pace, appetite, desire to eat.

The complex mealtime environment within a hospital required a pragmatic viewpoint to design a study that could be undertaken in a clinical ward environment, fully answer the clinically relevant research question, carry out pragmatic data collection in the real world and transfer results directly into clinical practice.

3.3.2 Introduction to the MRC complex intervention framework

Systematic development and evaluation of a complex intervention is highly recommended to support adoption of appropriate study design (Craig et al. 2008). To support this, the Medical Research Council (MRC) have published a highly cited framework (Campbell et al. 2000; Craig et al. 2008). The framework acknowledges that evaluations of complex interventions must overcome additional practical and methodological challenges and support researchers in identifying additional challenges associated with complex interventions (Craig et al. 2008).

The framework, outlined in Figure 3-1, considers four stages to evaluating a complex intervention. The MRC framework is the foundation of the study undertaken for this thesis and guided the overall approach of the intervention development and feasibility stages. The purpose of this thesis is to support the progression onto the evaluation stage through a future trial, evaluating the use of finger foods in hospitals. The thesis reports on the ‘intervention development’ stage and ‘feasibility and piloting’ stage outlined in Figure 3-1. These stages are paramount prior to full evaluation of a complex intervention (Craig et al. 2008).

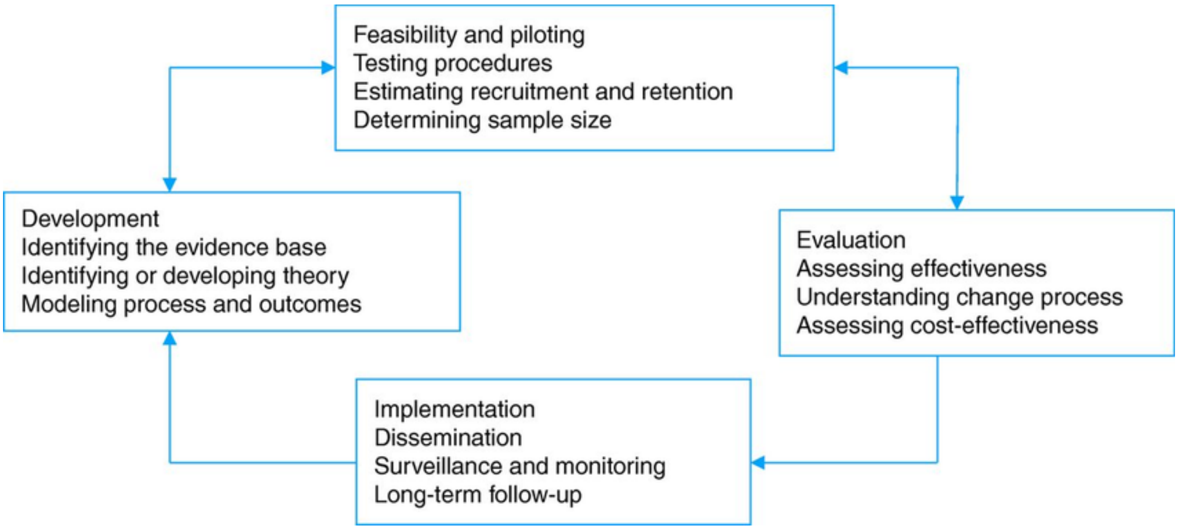


Figure 3-1 MRC complex intervention framework

The next section focuses on the intervention development stage of the study, dedicated to the finger food intervention development. This is followed the rationale for use of a feasibility study.

3.4 Development of the ‘finger food menu’ intervention

The MRC complex intervention framework defines the intervention development stage as ‘developing the intervention to a point to be expected that it will have a worthwhile effect’ (Craig et al. 2008 p. 9). The ‘intervention development’ is the stage between conceptualisation of the idea or intervention and feasibility testing (O'Cathain et al. 2019b). It involves designing, producing and delivering the intervention. The development stage is an iterative approach, which can be re-evaluated and altered before a full trial dependent upon results in the feasibility stage (Hoddinott 2015).

The PhD candidate began groundwork of developing and designing the intervention for this study in March 2018. The intervention developed for this feasibility study was a finger food menu designed for use on a stroke rehabilitation ward at an NHS hospital Trust. The aim of the intervention was to increase oral intake for people after stroke in hospital. Developing an intervention to fit the multifaceted complex hospital mealtime with considerations to the person, food, environment and overarching system policy and regulations is inevitably a complex process. To carefully consider these multifaceted components during development, guidelines for developing a complex intervention are recommended (Craig et al. 2008) to increase the chances of effective evaluation and implementation into clinical settings (O'Cathain et al. 2019b).

The highly cited MRC complex intervention framework and guidance provides a very brief overview of the 'intervention development stage' (Craig et al. 2008). Since the MRC complex intervention framework was first published (Craig et al. 2008), several guidelines have been produced to support researchers in systematically developing complex interventions, considering the multiple inter-relating components (Craig et al. 2008). These guidelines provide extension to the 'intervention development stage' presented by Craig et al. (2008) and provides researchers with additional information about how to develop a complex intervention (O'Cathain et al. 2019a). The guidance by O'Cathain et al. (2019b) describes key elements to robustly develop a complex intervention, acknowledging that there is currently no evidence suggesting that using a defined framework or approach is better than a pragmatic approach to development. The PhD candidate supports a pragmatic approach to intervention development, considering the context and the support of key stakeholders alongside a systematic approach. Each framework and guidance document used within this section serves a different purpose. Table 3-2 provides an overview of frameworks used within the thesis, reason for inclusion and how the framework is applied to the project.

Table 3-2 Overview of guidance and frameworks used to inform this feasibility study

Framework used in this thesis	Reason for inclusion	How the framework is applied to project
MRC complex interventions guidance (Medical Research Council 2006; Craig et al. 2008).	Provides a general framework and structured guidance on how to design and evaluate a complex intervention.	Used as an overarching framework to the study to justify the need for separate intervention development and preliminary study prior to full evaluation and implementation stage.
Guidance on how to develop complex interventions by O'Cathain et al. (2019b)	Specific guidelines developed alongside the MRC complex interventions guidance to support robust development of a complex intervention .	Elements identified by O'Cathain et al. (2019b) are used as subheadings to report on key stages to the development of the intervention. These include exploring the evidence base, involvement of stakeholders, modelling processes and outcomes, consideration of the context and system, describing theory of the problem and programme theory and economic considerations.
Making the most of mealtimes conceptual model by Keller et al. (2014)	Identifies multiple level factors that impact on a hospital mealtime and that need to be addressed to ensure success. Fits with outcomes addressed by the research study including food intake, mealtime experience, meal access and meal quality.	Supports identification of the components of a hospital mealtime as a complex intervention. Concepts identified in this model used as a framework to analyse field notes and to develop interview topic guide.
I - PARIHS framework (Harvey and Kitson 2015b)	Framework based on implementation science recognises the interplay between the key concepts of facilitation, innovation, recipients and context to successful implementation.	Used in the results and discussion section to reflect on facilitators and barriers to implementation and strategies to support success of the intervention delivery in a future study.

For this feasibility study, elements of the guidelines for robust intervention developed by O'Cathain et al. (2019b) were followed, which included:

- Exploring the evidence base
- Involvement of stakeholders
- Modelling processes and outcomes
- Consideration of the context and system

- Describing theory of the problem and programme theory
- Economic considerations

These are further discussed below, taking each element in turn.

3.4.1 Involvement of stakeholders

The involvement of stakeholders, including the patients and public, catering teams and clinical ward teams supported development and design of the components of the finger food menu intervention. Involving key stakeholders meant that uncertainties regarding what a finger food menu should comprise for people after stroke and how it should be delivered on the ward could be decided. Involving these key groups allowed knowledge and overview of the ward culture to be considered when developing the intervention and meant that potential barriers regarding the delivery of the intervention on the ward were confronted at an early stage. This also provided the opportunity for the PhD candidate to gain support for using the intervention on the ward.

3.4.1.1 **Input from patient and public involvement (PPI)**

The National Institute of Health Research defines patient and public involvement as “research carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them” (National Institute for Health and Research 2020). Activities included as PPI differ from those included as research and involve prioritising research questions, making comments to develop research materials and offering advice as members of a steering group (National Institute for Health and Research 2020).

For this feasibility study, the PhD candidate attended a community stroke group and invited members of the group to discuss priorities for using finger foods in hospital, to review methods set out in the proposal and discuss appropriate foods for the menu. Seven people who had experienced a stroke agreed to take part. To support members with communication difficulties, pictorial resources were made in an aphasia-friendly format and presented to the group. Due to different expressive communication modes of output from group members, notes were made by the researcher on key points raised by participants.

Participants at this consultation reported negative mealtime experiences during their hospital admissions. Some reported not being able to use cutlery and choosing the same meal on a daily basis, throughout a four month stay, to ensure they could easily consume it. The seven people who had a stroke (aged 50 to 86 years; three men and four women) showed interest and support for offering finger foods in hospital. The participants used a picture sorting task to choose hospital foods that they would be happy to consume with their fingers. All participants perceived no concerns with eating with their hands, if food was pre-prepared and cut up. Participants stated that all food provided should be well represented with a photo on the menu, so that food turned up on the ward as expected. This was described as key in supporting appetite and food intake.

3.4.1.2 Meetings with catering teams

The PhD candidate arranged two informal interviews with catering management to support the study setup and to develop the finger food menu. The hospital catering management agreed to support the project and the catering link dietitian, a dietitian who was employed by the commercial catering provider, agreed to support ongoing liaison throughout the data collection period.

The meetings with the catering team provided an opportunity for the researcher to discuss what foods the finger food menu should comprise and how the finger food menu could be delivered on the study ward. A pragmatic approach was required to ensure the delivery of the menu aligned with the current service delivery. The researcher agreed with the catering team that the menu would be trialled over lunchtime meals as hot food could be provided. It was agreed that an à la carte style menu, similar to the standard menu already in existence, would provide participants with a choice of available finger foods. The researcher arranged a separate meeting with the catering dietitian and ward host that regularly served food onto the ward to confirm how the ordering system would work on the ward.

Foods chosen for the finger food menu were based on the definition of a finger food provided in the literature and, pragmatically, what was made available by catering. Items already procured to the hospital could be repurposed as finger food and finger foods chosen were based on information provided during the consultation with stroke patients. To assess items for suitability, the PhD candidate and catering dietitian reviewed the current hospital menus and then completed a tasting session to confirm suitability of food items. Items were included as finger foods if they could be picked up and transferred to the mouth without the need for cutlery (Department of Health 2014; Buckinghamshire Health Care NHS Trust 2015).

The researcher agreed that a separate paper menu would be used and disposed of between participants to comply with infection prevention measures. The catering dietitian provided photos of food items to put on the menu to show what foods were available, as requested by the patient and public involvement group.

3.4.1.3 Meetings with clinical ward teams

During the initial phases of the menu development, the PhD candidate set up meetings with the clinical lead dietitian and clinical lead SLT for the stroke ward. The idea of developing a finger food menu for the stroke rehabilitation ward was discussed, including the plan to evaluate this using a feasibility and acceptability study. Team leads voiced their support for the study and intervention and saw the potential benefit this could provide to patients on the ward. Team leads disseminated this proposed plan to other colleagues during local team meetings and arranged timings and room bookings for an information session.

The researcher arranged a formal information session with SLTs and dietitians working on the study ward to provide the opportunity for the clinical teams to comment on the proposed intervention and provide comments or concerns. Overall, teams voiced their support for the intervention, acknowledging that reduced oral intake was often a challenge for patients on the ward and impacted on rehabilitation. Clinical staff raised concerns about ordering from a new menu and the reliability of the ward host to order and deliver the correct meal to the patient. It was agreed that the ward host should be provided with additional training and involved in engagement sessions prior to the roll out of the menu. Discussions were had about the suitability of the menu for people on a modified texture diet due to high prevalence of dysphagia. It was agreed that strict eligibility criteria would be in place to ensure that only patients managing a level 7 regular textured diet would be offered the menu. This is reflected in the eligibility criteria for this feasibility study, further described in section 4.4.1.1. It was agreed that all patients would be appropriate to trial the finger food menu, irrespective of their nutritional status.

The PhD researcher set up an additional meeting with the ward manager to discuss the study and to agree on the best way to communicate information about the project to clinical nursing staff and healthcare assistants. Due to the different shift patterns worked by staff, the ward leader suggested providing written communication via email as dictated by the PhD candidate to ensure all staff were aware of the new finger food intervention being trialled on the ward. This information was also cascaded to consultants working on the study ward via email.

3.4.1.4 How the PhD candidate’s role supported with key stakeholder input

The PhD candidate’s clinical academic role fostered relationships between the researcher and key stakeholders. This highlights the importance of the two roles not being mutually exclusive and shows that the clinical and academic components supported each other (NHS Health Education England 2017). Working as a clinician in the NHS Trust where the research was being carried out meant that the PhD candidate was able to identify key leaders in each area and easily make contact during the research process.

3.4.2 Mealtime observations

As part of the development phase of a complex intervention, guidelines published by O'Cathain et al. (2019a) suggest undertaking primary data collection and fully understanding the context in which the intervention will be used. Non-participant observations supported understanding the research context alongside engagement with stakeholders to fully acknowledge the wider complex health care system (O'Cathain et al. 2019a).

Prior to the study set up, the PhD candidate conducted two mealtime observations on the ward, where she shadowed the catering ward host serving the food and observed patient and staff interactions. This was deemed the most appropriate way to capture information required about the mealtime service and delivery process on the ward as the ward host worked short shifts where they were required to deliver and serve meals only.

Field notes were captured on an informal observation tool developed by the researcher. The tool captured quantitative information regarding the number of patients on the ward, the number of patients recommended a level 7 ‘regular’ diet, timings of lunch service and which members of staff were supporting during lunchtime meals. In addition, qualitative notes were made regarding the ordering system and any comments made by clinical staff regarding mealtimes or feeding. The ward host showed the PhD candidate how the ordering system worked on the tablet and worked with the PhD candidate to develop a process for ordering food on the tablet system.

3.4.3 Training provided for the catering team

The researcher acknowledged, during discussions with the ward host, that some of the foods on the finger food menu required alternative cooking times to the food that was already provided on the ward. The catering link dietitian agreed to provide training to the two members of the catering staff who regularly heated and served meals on the study ward. The training included information about the foods offered on the finger food menu, time frame for the study period and information on how to cook items that were not typically served on the ward. The process for ordering the food onto the ward was shown to the ward hosts responsible for ordering food onto the ward.

3.4.4 Modelling processes and outcomes in a logic model

Based upon input from key stakeholders a logic model was formulated to graphically represent how the proposed intervention worked within a specified context. Table 3-3 shows the logic model developed for using finger foods on a stroke rehabilitation ward. This logic model simplifies the complex intervention into four headings (The Department of Health 2018):

- Considering the situation – e.g., the context, problems and needs
- Resources/inputs – required to carry out activities identified
- Activities/outputs – key areas to achieve the desired outcomes
- Outcomes – specific changes required in short and long term.

Table 3-3 Logic model for using finger food menu on stroke rehabilitation ward

Situation analysis	Resources/Inputs	Activities/outputs	Outcomes
• People after stroke often have eating difficulties which are not targeted with intervention **(Poels et al. 2006)**. • Eating difficulties in people after stroke cause increase in dependence with eating and high rate of malnutrition in hospitals **(Elia 2015; Burgos et al. 2018)**. • All patients in NHS hospitals are entitled to appropriate nutrition in hospital with adequate assistance **(Care Quality Commission 2017)** • Assistance provided by family or staff can vary • Finger foods are recommended in BDA guidelines for hospitals, currently not consistently provided and limited evidence of effectives in hospitals **(Heelan et al. 2019)**. • Food acceptability can be based on patient background and social norms	• Materials for design and printing of finger food menu • Engagement with stroke survivors • Engagement with catering team, dietitians • Time for training catering staff regarding roles when delivering finger food meals • Nutrition and cost data of finger foods.	• Develop menu with stakeholder input • Gain support from ward leader and catering manager • Source food items for menu. • Information provided on the use of finger foods to promote staff engagement. • Delivery of training to support ward host with ordering and presentation • Use finger food menu on the ward with patients • Mealtime observations and data collection of standard practice and intervention implementation.	*Short-term outcomes* Process outcomes • Feasibility of implementing finger foods • Acceptability of finger foods to patients and staff • Safety concerns Service outcomes • Acceptable menu to patient group • Costings of finger food • Support from staff required Client outcomes • Changes in dietary intake • Changes in meal experience • Changes in meal access *Long term outcomes* • Cost implications • Resource implications • Dietary intake • Patient mealtime experience

None of the studies from the review in Chapter 2 included references to intervention development based upon theory. However, the logic model in Table 3-3 can support the theoretical understanding between each stage of the model and conceptualise the intervention within a complex system (Moore et al. 2019). Logic models can be used to show processes in which an intervention affects change on a person or proposed outcomes (Kneale et al. 2015) and therefore can be used to support selection of relevant theories to explain the relationship between the variables.

It is important to recognise the components of an intervention which have been used to address similar problems elsewhere and use theory to understand how these components work together to impact the desired outcome (Moore et al. 2019). Theory is defined as assumptions that explain the relationship between causes and outcomes. Theories are tested using empirical data and can originate from the evidence base, experience, common sense or ideology (Moore et al. 2019).

3.4.5 Programme theory

For this study it is important to recognise theories that help us to understand the causal changes between the 'activities/outputs' of the finger food menu intervention and outcomes generated as described in Table 3-3. This is recognised as best practice to identify how the intervention works, why it works and what is causing changes in outcomes (Craig et al. 2008). Programme theory should consider mechanisms of change, implementation and context.

Models by Ottrey et al. (2020) and Keller et al. (2014) usefully describe theory in relation to nutritional intervention development and implementation. Both models place emphasis on multiple levels of hierarchical influence and interrelations between personal and environmental factors and eating based upon the systems theory of structure of the social ecological model first described by (Bronfenbrenner 1977).

The conceptual model by Keller et al. (2014), presented in Section 1.7, describes three domains that influence food intake: meal experience, meal quality and meal access, with overarching domains including the individual's needs, the environment and influences of government on policy, guidelines and regulations. Keller et al. (2014) suggest that development of nutritional interventions should consider multiple levels of the model to gain success, as there is not one component that is shown to individually impact on food intake. For example, the provision of finger foods alters meal access by providing foods that do not require cutlery and that can be eaten with the hands (Keller et al. 2014). However, on a wider scale, food availability is dictated by the hospital catering provider. Therefore, it is important to consider the overarching influence of the catering provider and hospital system on intervention outcomes. All levels of the hierarchy are considered within this logic model.

Ottrey et al. (2020) highlight the importance of considering the relationship between the intervention, individual, organisational and structural factors when implementing a mealtime intervention in a complex hospital environment (Ottrey et al. 2020). The model by Ottrey et al. (2020) illustrates findings from an ethnographic study exploring staff experiences during implementation of a nutritional intervention in hospital, based upon implementation theory. Ottrey et al. (2020) based the model on the ‘protected mealtimes’ intervention, however acknowledged that all interventions to improve nutritional care need to consider targeting multiple factors at multiple levels. Ottrey et al. (2020) concluded that staff engagement and staff perceptions of change should be addressed when implementing changes, including their understanding of the need for change, communication and collaboration (Ottrey et al. 2020). During the development of the finger food menu intervention, engagement with staff played a key role in the activities and resources used. Prior engagement activities with various members of staff likely supported staff to feel positive about the change, deemed key to supporting the implementation (Ottrey et al. 2020). The associated paper by Porter and Ottrey (2018), describes a process evaluation of implementing protected mealtimes in hospital and acknowledges that fidelity is impacted by the extent to staff training and staff resources.

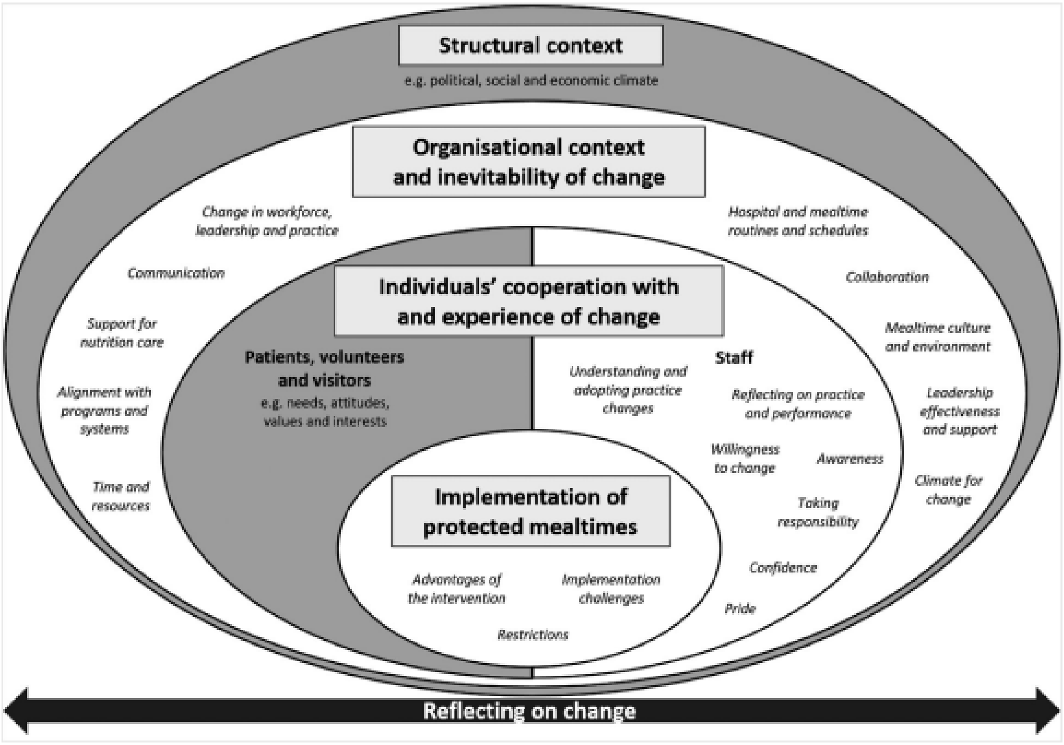


Figure 3-2 Mealtime intervention implementation model.

Reprinted from Journal of Human Nutrition and Dietetics, 33(4), by E. Ottrey, C. Palermo, C. E. Huggins, et al, title: A longitudinal ethnographic study of hospital staff attitudes and experiences of change in nutrition care, page: 10, (2020), with permission from John Wiley and Sons.

Ottrey et al. (2020) report the use of implementation science to summarise the findings regarding staff attitudes and beliefs towards change in nutrition care and experiences of intervention implementation, citing work by Chaudoir et al. (2013), Damschroder et al. (2009) and Harvey and Kitson (2015b). The work by Chaudoir et al. (2013) reports on the development of a five-factor framework used to assess constructs relating to structural, organisational, provider, patient and innovation level outcomes, all hypothesised to affect implementation outcomes. Damschroder et al. (2009) report on the Consolidated Framework for Implementation Research (CFIR), a framework comprising of five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. As detailed further in section 2.5, Harvey and Kitson (2015a, 2015b) describe the development of the PARIHS framework to support implementation, which focuses on evidence, context and facilitation. More recently, the PARIHS framework has been further developed to become a more coherent and comprehensive framework and re-named the integrated-Promoting Action on Research Implementation in Health Services (I-PARIHS framework) (Harvey and Kitson 2015a). This framework argues that successful implementation is due to interplay between the key concepts of facilitation, innovation, recipients and context. Innovation has been used to replace ‘evidence’ acknowledging that evidence can be incorporated in many ways and recipients added as an additional concept to incorporate the views of users and reviewers at both individual and team levels. Ottrey et al. (2020) do not describe fully how the concepts defined in these three frameworks based on implementation science were used in the analysis of the results. However, the overview is used to further consider how implementation science frameworks could support reporting the findings from this feasibility study.

The multifaceted considerations to intervention implementation can be drawn upon for the development of the finger food menu intervention and included in the activities of the logic model. It is important to consider the specific context in which the intervention is being tested, to support with scaling up or using the intervention in different contexts. O'Cathain et al. (2019b) support understanding the context in which the intervention is developed and highlight the importance of addressing the acceptability of the intervention at multiple levels. The context can be considered the team, department or organisation in which the intervention sits (Nilsen and Bernhardsson 2019). The relevance of context within implementation science has been discussed in numerous implementation science frameworks, including the Promoting Action on Research Implementation in Health Services (I-PARIHS) framework (Harvey and Kitson 2015a). The implementation science literature considers barriers and facilitators of context that impact on the implementation of an intervention, of which, some barriers in one place may facilitate it in others (May et al. 2016). Understanding these are deemed important in understanding why some interventions are well implemented in clinical practice (May et al. 2016).

Nilsen (2015) describes the I-PARIHS framework as a determinant framework which aims to understand or explain influences on implementation outcomes, considering individual determinants which act as barriers or enablers. The focus on key concepts of context and facilitation resonates with this feasibility study, considering the role of the PhD researcher in the study acting as the facilitator and the importance of the context and interrelated components of a hospital mealtime (hospital system and food service system) presented in section 3.3.1. . Concepts highlighted by the I-PARIHS framework allowed the PhD candidate to consider which characteristics of the context facilitated or proved to be a barrier for successful implementation and which tools facilitated the support of the intervention. The concepts from the I-PARIHS framework (Harvey and Kitson 2015a) are used to categorise the findings from the mealtime observations and intervention development phase, identify key barriers and facilitators and create a table of recommended implementation strategies.

3.4.6 Contextual considerations

The MRC complex interventions guidance suggests taking account of context in which the intervention is being implemented (Craig et al. 2008). This section provides an overview of the setting in which the finger food menu was implemented.

An external catering company was contracted to provide hospital meals at the study site. The NHS hospital and catering team were required to abide by food and drink standards set by the UK Government as discussed in section 1.8 on page 36 and to meet key recommendations made by the British Dietetic Association (The British Dietetic Association 2017). The recommendations include menus that meet pre-defined nutrient standards, menus that are designed and structured for the population and including specific religious, cultural, vegan and gluten free menus, menus appropriate for therapeutic and modified diets and the provision of two snacks per day (The British Dietetic Association 2017).

Hospital Trusts in the UK operate different models of catering provision for patients, visitors and staff (Gray et al. 2017). Within NHS Trusts, models range from on-site cooking to ready-made meals regenerated and delivered by either NHS employees or external contractors (Gray et al. 2017). In recent years, many hospital catering services have moved from traditional ‘cook-serve’ methods (where food is prepared and made on site) to ‘cook-chill’ or ‘cook freeze’ methods, where food is pre-prepared, chilled or frozen and regenerated at ward level. This means that infrastructure for catering provisions in hospitals has reduced, with most food for patients being provided by external companies in large regional factories, then delivered as ‘cook-chill’ or ‘cook-freeze’ to hospital settings to be reheated on the ward (Gray et al. 2017).

The hospital site for this study used a ‘cook freeze’ method for delivering food to patients. Patients were served three meals a day (breakfast, lunch and supper) and provided with choices from an á la carte menu. Snacks were provided between meals and hot and cold beverages were provided throughout the day. Ward hosts employed by the external catering company were responsible for taking food orders for patients each morning. This was recorded on an electronic tablet and sent to the back of house freezer, where items required for each ward were picked and packed. The ward host was responsible for collecting the items and putting them in the oven to be heated and served on the ward. Serving on the ward was co-ordinated with a clinical member of staff, typically a housekeeper or health care assistant.

Because of the set-up of the study site, foods provided on the newly developed finger food menu were limited to food items already bought in by the Trust. This meant the cooking mechanisms and delivery mechanisms at the ‘hospital systems’ level did not require alteration. There were many items that could be adapted and served as finger foods and many of the finger food items that were used on the finger food menu were items previously only offered on children’s wards (e.g., fruit slices and pizza). In some instances, some of the food items that were on the standard menu were also appropriate to be on the finger food menu, e.g., sandwiches, baby carrots and chips. This meant that cross-over between menu items existed and some food items were offered on the finger food menu and the standard menu. These items were included on both menus as a pragmatic choice and to increase the options available on the finger food menu. The finger food menu differed from the standard menu with regards to how food items were offered. Specifically, items on the finger food menu could be ordered more flexibly, including participants choosing multiple items, e.g., sandwich, chips and baby carrots, which was not offered within the standard menu. Figure 3-3 and Figure 3-4 shows the finger food menu produced for the study. Participants offered the finger food menu were able to choose either a hot food or sandwich and up to three vegetable or sides and two dessert options.

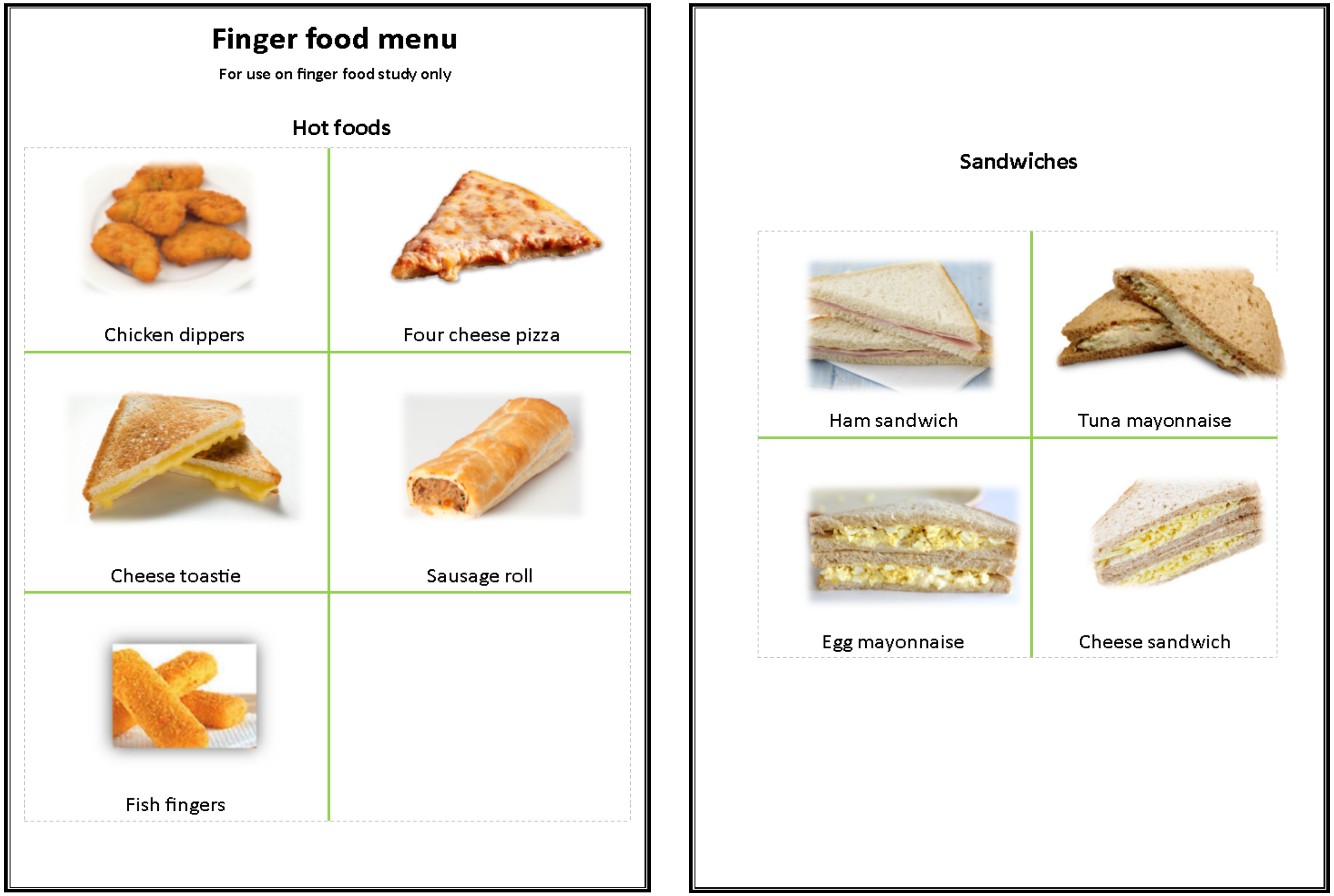
3.4.7 Menu design

Design is reserved for the point of development where developers make decisions about format, content and delivery (O'Cathain et al. 2019b). For this study finger foods were defined as foods presented in a form that are easily picked up with the hands and transferred to the mouth; without the need for cutlery (Department of Health 2014; Buckinghamshire Health Care NHS Trust 2015). These three key decision areas for the design of the finger food menu are considered below.

Format: A pictorial menu was developed by the PhD candidate following guidelines from the National Institute of Health Research for creating aphasia friendly resources (NIHR 2018) and based upon images collated from the catering companies' pictorial resources and menu formats already used within the hospital. The menu was printed as an A3 folded sheet on two pages. This meant that each participant had their own copy which could be disposed of after use to ensure adequate infection prevention measures. Menu items were presented as main items, split into hot and cold foods, side dishes and desserts as shown in Figure 3-3 and Figure 3-4 (page 91).

Content: The content of the menu was confirmed in liaison with the hospital catering team. Menu items included were items already available and procured by the hospital Trust, which were re-purposed to use on the finger food menu. Foods had been pre-checked for nutritional values and information regarding allergens was already available. By using food already obtained by the hospital Trust, regeneration timings and procedures were already in place.

Delivery: The menu was provided to participants prior to meal ordering. The PhD candidate was available at the time of meal ordering to support participants and answer any questions. Participants were offered one main dish, two side dishes and up to two dessert items. These items were selected from the paper menu and then entered to the catering ward host's electronic tablet. Through the tablet, orders were sent to the distribution centre within the hospital so that the items could be picked and packed and then sent up to the ward for regeneration prior to serving. Meal trays were delivered to participants alongside the standard meal trays. Participants were provided with hand wipes on their meal tray, as per standard practice. Ward hosts serving the meals had received additional training (described in 3.4.3).



Finger food menu

For use on finger food study only

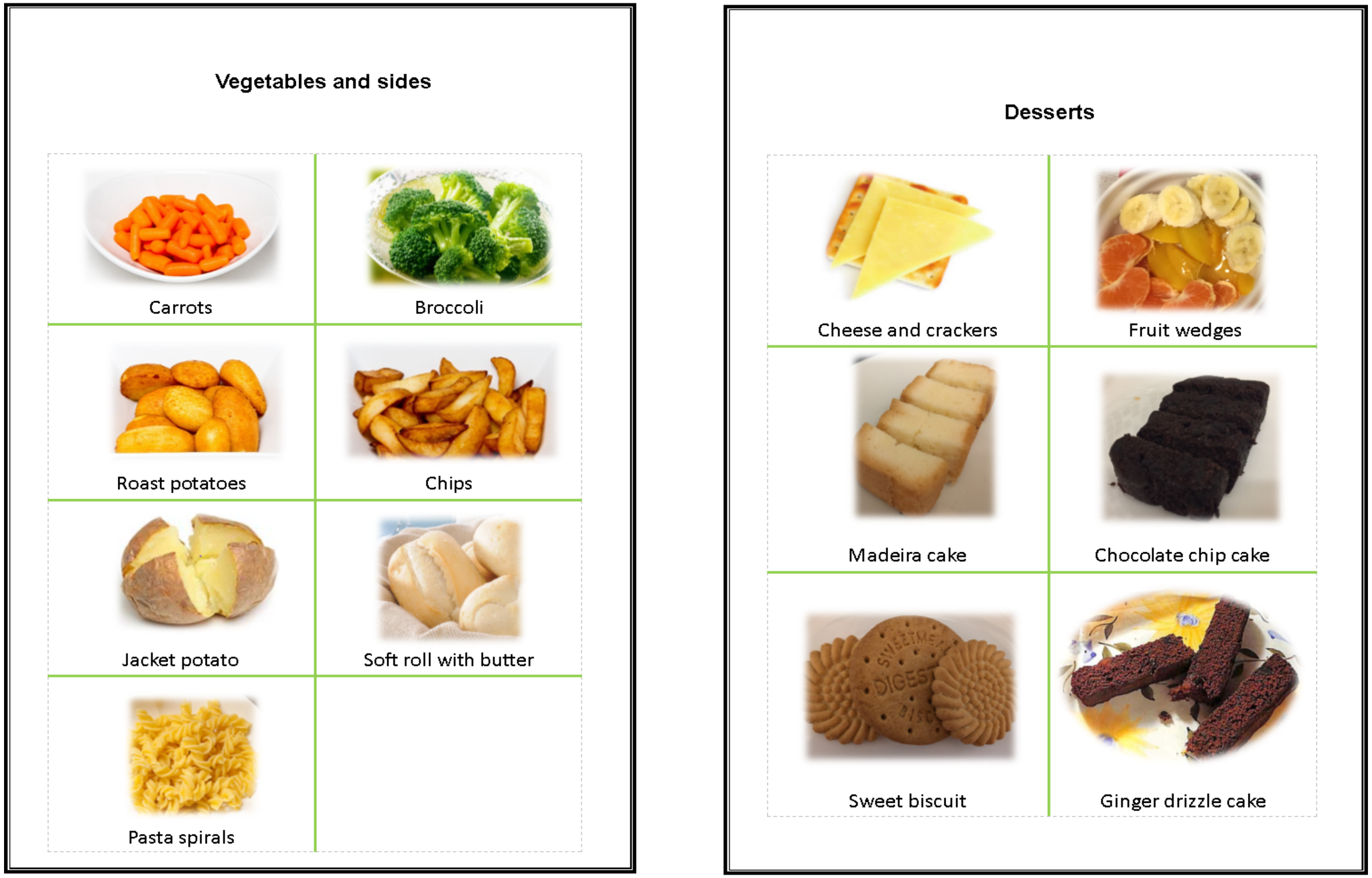
Hot foods

Chicken dippers	Four cheese pizza
Cheese toastie	Sausage roll
Fish fingers	

Sandwiches

Ham sandwich	Tuna mayonnaise
Egg mayonnaise	Cheese sandwich

Figure 3-3 Finger food menu, page 1



Vegetables and sides

Carrots
Broccoli
Roast potatoes
Chips
Jacket potato
Soft roll with butter
Pasta spirals

Desserts

Cheese and crackers
Fruit wedges
Madeira cake
Chocolate chip cake
Sweet biscuit
Ginger drizzle cake

Figure 3-4 Finger food menu, page 2

3.4.8 Economic considerations

A cost consequence analysis can use a wide perspective (Hunter and Shearer 2019) including NHS services, local government and family caregivers. This reflects the wide remit and breadth of sectors involved in the intervention (Edwards and McIntosh 2019a). The wide perspective also ensures transparency, despite providing a harder task of identifying all costs and benefits to all parties.

The intervention (finger food menu) was compared with the standard menu offered to people after stroke in hospital with regards to food item costs as shown in the following table (Table 3-4). Key resources identified for implementation include the food provided and staff time for preparing, delivering, and providing mealtime support or feeding. Information was gathered from the catering team providing the foods. Key resources required for the intervention were discussed with relevant stakeholders, including catering teams and NHS staff to gain their agreement and engagement.

Table 3-4 Direct and indirect costs associated with intervention

Perspective	Cost category	Types of cost	Description	Potential sources of data
Catering provider	Intervention cost	Direct	Production and printing of additional menu	Data from catering team
	Intervention cost	Direct	Food costs	Food cost data from catering team
	Intervention cost	Indirect	Time required for ward host to prepare finger food meal trays.	Interviews with catering team Ward observations
Hospital provider	Staff training	Direct	Staff training to support understanding of finger food and who to use it for	NHS costings for staff time to deliver training
	Staff support over mealtimes	Indirect	Staff costs relevant to time required to support patients over mealtimes.	Mealtime observations
Family caregivers		Direct	Food provision bought in by the family	Observations on the ward Interviews with patients

The relevant outcomes for the intervention should be considered post trials.

- Food intake
- Plate waste
- Patient satisfaction – engagement with eating, experiences, independence with eating
- Assistance required from staff
- Rates of malnutrition
- Requirement for oral nutrition support or enteral nutrition
- Length of hospital stay
- Complications associated with malnutrition

This section provided details regarding the direct and indirect costs associated with the nutritional intervention. The feasibility study presented in this thesis trialled data collection methods to support decision making regarding an economic assessment for a future trial.

3.5 Rationale for a preliminary study

The previous sections in Chapter 3 focus of the development of a finger food menu. Due to the associated uncertainties about what a future study should look like to evaluate the menu in hospital for people after stroke, a preliminary study is recommended. The MRC complex interventions framework (shown in Figure 3-1) advocates for pilot and feasibility studies both being types of preliminary study (Craig et al. 2008). The guidelines use the terms ‘feasibility’ and ‘pilot’ interchangeably, alongside much of the other literature and theory in this field (Craig et al. 2008; Eldridge et al. 2016a). In line with the PhD candidate’s viewpoint, The National Institute of Health Research (NIHR) describes feasibility and pilot studies as distinct studies with their own purpose and have usefully developed clear guidance on the differences between the two (Williams 2016).

3.5.1 Distinguishing between a pilot and a feasibility study

The NIHR describes a pilot study as a small-scale version of the main study. According to the NIHR, the purpose of a pilot study is to test the key processes in preparation for the main study (e.g., the recruitment, randomisation and intervention) to ensure that they work together and operate smoothly (Williams 2016). The design of a pilot study resembles the main study and aims to evaluate the primary outcome (Williams 2016).

In contrast to this, feasibility studies are defined as studies completed prior to a main study to establish whether larger studies can be delivered (Williams 2016). They simply ask, ‘can the study be done?' (Bowen et al. 2009; Bugge et al. 2013). They are used to estimate important parameters for a main study and make a good basis for deciding whether future study should be funded and how to proceed (Moore et al. 2018). Typically, feasibility studies do not follow the same design as the main study and the primary outcome is not evaluated (Williams 2016).

3.5.2 Rationale for feasibility study

A feasibility study was conducted to address specific uncertainties surrounding the evaluation of the effectiveness of a finger food menu intervention in hospitals. It was used to understand whether a larger future study is viable and warranted (Craig et al. 2008) and to ensure that a future evaluation study would be robust and feasible (Eldridge et al. 2016b).

Despite some debate regarding the usefulness of feasibility studies, Morgan et al. (2018) concluded that they are useful to save time and money prior to conducting a full evaluative trial. Considering that large multi-centre randomised control trials to examine the effectiveness of an intervention are costly and time-consuming, data from preliminary pilot/feasibility studies is often a requirement from large funding bodies before allocation of research money (Lancaster et al. 2004).

3.6 Setting objectives of the feasibility study

The NIHR makes it clear that objectives of a feasibility study differ from the objectives of a pilot study (Williams 2016). To support the dissemination of feasibility studies, specific guidelines for reporting have been published, making it clear that *a-priori* objectives must be set (Lancaster et al. 2004; Thabane et al. 2010; Bugge et al. 2013; Lancaster 2015). The objectives of the feasibility study should address gaps in prior knowledge and aim to acknowledge whether a future trial can be delivered (Williams 2016). During a feasibility study, formal hypothesis testing for effectiveness is not recommended as it will be underpowered and therefore not represent a true result (Eldridge et al. 2016a).

The evidence-based guidelines by Lancaster et al. (2004) suggest that clear study objectives add methodological rigour to external pilot studies, and should include objectives to:

- Test the integrity of the study protocol for the future trial
- Gain initial estimates for sample size calculation
- Test data collection forms or questionnaires
- Test randomisation procedure(s)
- Estimate rates of recruitment and consent

- Determine the acceptability of the intervention
- Select the most appropriate primary outcome measure(s)

In 2015, O'Cathain et al. (2015) extended thinking in this area to highlight the important impact qualitative data can add to feasibility studies. O'Cathain et al. (2015) developed guidance for producing objectives for mixed methods feasibility studies, based on experience and systematic mapping review of the literature. Setting objectives for a mixed methods feasibility study should focus on listing and prioritising key uncertainties relating to the overarching categories as outlined in Table 3-5.

Table 3-5 Key uncertainties for feasibility studies based on O'Cathain et al. (2015).

Overarching categories	**Key uncertainties described by O'Cathain et al. (2015).**
Trial design, conduct and processes	• Recruitment and retention • Diversity of participants • Trial participation • Acceptability of the trial in principle and in practice • Ethical conduct • Adaption of the trial conduct to local context • Impact of trial on staff, researchers, participants and health systems • Patient and public involvement
Intervention content and delivery	• Intervention development • Intervention components • Mechanisms of action • Perceived value • Benefits, harms or unintended consequences • Acceptability of the intervention in principle, Feasibility and acceptability of intervention in practice • Fidelity, reach and dose of intervention
Measures	• Accuracy of measures • Completion of measures • Development of measures
Outcomes	• Breadth and selection of outcomes

Considering the lack of literature evaluating the use of finger foods in hospitals and recommendations made for future study to use a mixed methods design (Heelan et al. 2019), the overarching categories, as described in Table 3-5, are appropriate to develop objectives for this feasibility study. Priority uncertainties from each of the four overarching categories were taken forward to develop research objectives. For example, taking the overarching category of 'Trial design, conduct and categories', it was not known whether or not there was a sizeable population willing to trial the intervention and participate in the research and therefore it was important to evaluate recruitment and retention rates. In addition, it was unknown whether the planned recruitment practices would recruit the desired range of participants for the trial and therefore this study was required to define study samples (O'Cathain et al. 2015).

In view of 'intervention content and delivery', the limited literature surrounding the use of finger foods for people after stroke in hospital (Heelan et al. 2019) meant it was important to test the acceptability of the intervention for this patient group and to describe how the intervention was delivered on the study ward. Because the intervention components and mechanisms of actions had already been described within the intervention development stage, it was not felt necessary to carry these subcategories forward. In considering 'Measures' and 'Outcomes', the limited reporting of accurate and appropriate outcomes in previous research led to the requirement for the feasibility study to understand and test the measures and outcomes to ensure that they were accurate and that the data collection methods could be used on the study ward.

Based on the framework by O'Cathain et al. (2015) in Table 3-5, and recognising these key uncertainties, specific research objectives were developed which are presented in Table 3-6.

3.6.1 Aims and objectives

The aim of the study presented in this thesis was to establish the feasibility, acceptability and implementation cost of using a finger food menu with people after stroke to inform important parameters for a future randomised control trial. Table 3-6 defines the research objective within each category, with data collection method displayed. For this feasibility study a mixed methods approach was deemed appropriate to answer the objectives (O'Cathain et al. 2015).

Table 3-6 Research objectives for feasibility study

Category	Subcategory	Research objective	Data collection method
Trial design, conduct and processes	Recruitment and retention	**To define recruitment and retention rates.**	Quantitative
	Diversity of participants	**To define participant diversity.**	Quantitative
	Sample size	**To anticipate sample size for a future larger study.**	Quantitative
	Ethical conduct	**To determine the suitability of the consent process for people after stroke.**	Quantitative
Intervention content and delivery	Intervention development	**To describe whether the intervention was delivered as expected and determine whether any alterations to the intervention content and/or delivery are required.**	Qualitative
		To determine the direct and indirect costs to using finger foods in hospital compared to standard meal.	Economic evaluation
	Feasibility and acceptability of intervention in practice	**To explore patients and staff experiences of using finger foods on the stroke rehabilitation ward.**	Qualitative
Measures	Completion of measures	**To determine whether proposed data collection methods are appropriate.**	Quantitative
	Accuracy of measures	**To describe the median value and variability of dietary intake of a standard meal and finger food meal.**	Quantitative
		To determine the inter-rater reliability of using digital photographs to estimate dietary intake.	
Outcomes	Breadth and selection	**To determine whether outcomes chosen are appropriate to the study.**	Quantitative

3.6.2 Economic evaluation as part of feasibility study

One of the objectives of this study was to determine the costs and consequences of using finger foods in hospital. With any economic assessment of healthcare, it is important to consider the true direct and indirect costs of the intervention, to clearly describe the benefits to the service and be clear about the perspective in which the cost and benefits are adopted (McMahon and Sin 2013). Economic evaluations provide a framework which can be used to identify costs and benefits (Edwards and McIntosh 2019a). Not all that is measured can be monetised and benefits can be practical in nature. The assessment must aim to capture holistically all benefits identified (McMahon and Sin 2013).

Healthcare interventions must ensure efficient use of resources and greatest health benefits to patients (NICE 2012a). The report by Elia et al. (2006) shows the cost of disease-related malnutrition in England and acknowledged the importance of economic assessments to support the use of future recommended nutritional interventions, considering that adequate nutrition can potentially save money in the long term (Elia et al. 2006).

Feasibility studies can be used to develop or define service use schedules and outcome measures, and trial economic data collection methods for future economic evaluations (Hunter and Shearer 2019; Hounsome and Shearer 2020). It is not recommended that feasibility studies provide preliminary estimates of cost effectiveness due to their increased variability and small sample sizes. Conducting a full economic evaluation as part of a feasibility study risks bias to outcomes that may jeopardise future applications for definitive trials (Hounsome and Shearer 2020).

A cost consequence analysis was used for this feasibility study as recommended by the NIHR (Hounsome and Shearer 2020). A cost consequence analysis outlines the most relevant costs and outcomes for a future trial. It considers direct and indirect costs that influence the efficiency and effectiveness of an intervention and clearly outlines who benefits from what (Brazier et al. 2017). The results of the analysis are reported clearly in a table (NICE 2012a) but are not specifically monetised. The results rely on the decision maker to select the best valued intervention, based on the structured results (Brazier et al. 2017).

3.6.3 Mixed methods approach to feasibility study

As seen in Table 3-6, the objectives proposed in this study required quantitative and qualitative data collection methods to understand how the intervention will cause change, using a range of measures (Craig et al. 2008). A mixed methods approach was chosen to analyse, combine and integrate both quantitative (statistical data) and qualitative data (non-numeric data in the form of words including personal experiences and stories) to address the research question and enable deeper understanding about certain aspects of the research (Creswell and Plano Clark 2018).

Typically, feasibility studies include collection of qualitative data alongside quantitative data to help refine the intervention, improve the study design and support selection of appropriate outcomes (O'Cathain et al. 2015). The value of qualitative research methods within feasibility studies is highlighted by Craig et al. (2008) to refine comprehension of the intervention processes and support continuing adaptation of intervention and evaluation design in preparation for a full trial (O'Cathain et al. 2015).

For this feasibility study, a sequential mixed methods design was used (Creswell and Plano Clark 2018). Creswell and Plano Clark (2018) defines two types of sequential designs: **explanatory** (using qualitative data to explain and broaden the initial quantitative phase) and **exploratory** (qualitative data used to direct the next stage of quantitative methods) (Creswell and Plano Clark 2018). The intention of this research was to use qualitative interview data to support explanation of quantitative feasibility data. This enables the qualitative data and analysis to refine and explain numerical results by exploring participant's views in more depth (Creswell and Plano Clark 2018). Figure 3-5 visually displays the sequential mixed methods design applied to the overall research study. Equal weighting was provided to each of the elements to understand and answer the different research questions posed.

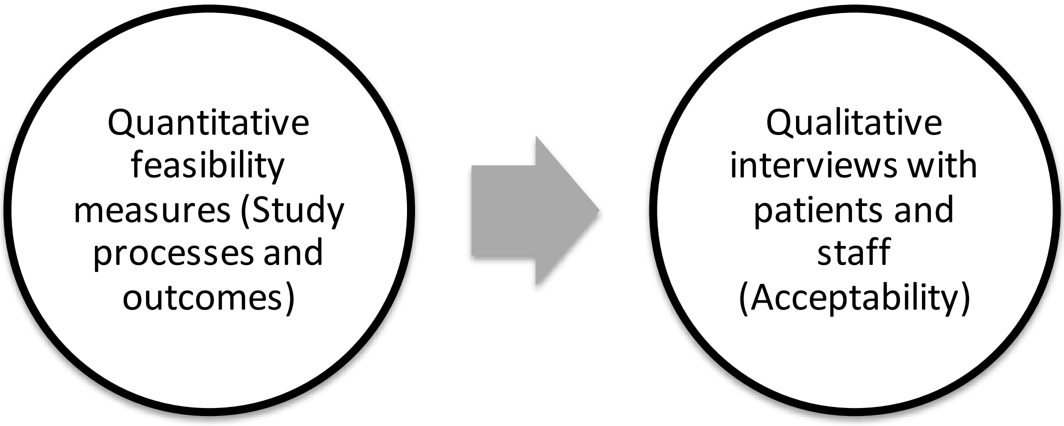


Figure 3-5 Visual display of sequential mixed methods design applied to the research study

The following chapter, Chapter 4, displays the full quantitative and qualitative data collection methods used as part of this feasibility study.

3.7 Chapter conclusion

The research study presented in this thesis was approached with a pragmatic viewpoint by a clinical academic PhD candidate who is a SLT. The complexity of the hospital environment and patient factors impacting on eating and drinking provide necessity for use of the MRC complex interventions framework (Craig et al. 2008) to approach the development and evaluation of the intervention in a systematic way.

As per the recommendation made in Chapter 2, this chapter has provided evidence to how the proposed finger food menu intervention was developed and displayed a logic model to indicate how the proposed intervention works in the hospital context for this study. The complex interventions framework was used to as a rationale for a feasibility study and a basis for 'the intervention development'. This chapter described a feasibility study as essential in providing information for a future, larger trial and has outlined key components to a feasibility study alongside the setting of study objectives.

Based upon the key objectives set and mixed methods approach described, the next chapter (Chapter 4) will outline methods used within the feasibility study using both quantitative and qualitative components.

Chapter 4 **Methods for feasibility study**

4.1 Introduction

As proposed in Chapter 3, the MRC complex interventions framework advocates for a feasibility study to be undertaken prior to evaluation of effectiveness (Craig et al. 2008). In 2016, CONSORT guidelines for reporting randomised control trials were updated and extended to include the reporting of pilot and feasibility studies (Eldridge et al. 2016a). At this time, the CONSORT group recognised that there was an increasing number of pilot and feasibility studies being published but that they were often inadequately reported. The guidelines' aimed to ensure transparency and robust reporting of feasibility and pilot studies so that future trials and other researchers could use the results to address similar work (Thabane et al. 2010).

Headings from the CONSORT checklist extension for pilot and feasibility studies (Eldridge et al. 2016a) have been used in chapter four to present the detailed methods for this feasibility study. The checklist is presented in Appendix F. The chapter combines both quantitative and qualitative research methods used within the study to answer a-priori research objectives previously stated.

This mixed methods feasibility study includes two main components, in which methods are addressed simultaneously. The two components are:

1. A prospective, before and after intervention study to address the feasibility of conducting a future trial to evaluate the effectiveness of using finger food for people in hospital. This included assessment of study processes, outcomes, and intervention delivery.
2. A qualitative study to address the acceptability of the finger food intervention using semi-structured interviews with patients and staff

Initially, research objectives relating to each component of the study are stated, with the overall study design. Subsequently, each heading of the CONSORT statement is presented and key details relating to research methods discussed. The chapter concludes with research governance and ethical issues addressed prior to data collection.

4.2 Research aim and objectives

As stated in 3.6.1, the aim of this study was to establish the feasibility, acceptability and implementation cost of using a finger food menu with people after stroke to inform important parameters for a future randomised control trial. The objectives for this study outlined in Table 3-6 on page 98 are presented in Table 4-1 with the corresponding research stage. In addition to these objectives, a preliminary indication to the effect on dietary intake of a standard meal vs the finger food menu provided is stated.

Table 4-1 Research stage and objective

Research stage	Research objective
Feasibility (study processes, outcomes and intervention delivery)	**To define recruitment and retention rates and participant diversity.**
	To define anticipated sample size for a future larger study.
	To determine the suitability of the consent process for people after stroke.
	To determine outcome measure completion rates to show whether data collection methods are appropriate to undertake on the study ward.
	To describe whether the finger food menu was delivered as intended on the stroke rehabilitation ward alongside the standard menu and determine whether any alterations to content and/or delivery are required.
	To determine the costs associated with using finger foods compared with the standard menu.
	To determine whether data measures are appropriate, accurate and reliable to address the primary outcome.
	To determine whether outcomes chosen are appropriate to the study
Acceptability	**To explore patients and staff experiences and acceptability of using finger foods on the stroke rehabilitation ward.**

4.3 Study design

This feasibility study was a prospective, before and after intervention study. The study employed a pre-test and post-test design with no comparison or control group. Data collection methods were chosen to answer research questions and test uncertainties for a future follow up trial (Williams 2016). A ‘pre-test and post-test’ design was deemed a low cost, convenient method to gather data with practical advantages. This design takes a pragmatic approach to ensure maximum success of data collected and using the most rigorous design.

Different study designs were considered when writing the study protocol. It was important to choose a design that best answered the research questions and would work pragmatically in the hospital environment. To support the design stage and ensure that the study was appropriate, the views of patients and public involvement group contributors were included. Appendix G provides an outline of alternative study designs considered, with explanations on advantages and disadvantages of each approach. No changes to the study protocol and study designs were made after trial commencement.

4.4 Participants

4.4.1 Participants involved in ‘before and after’ intervention study

Thirty-one consecutively admitted, eligible patients were recruited from a stroke rehabilitation ward in an NHS hospital on the south coast of England. This section sets out eligibility criteria, setting and in-depth information regarding how participants were identified and provided consent for the ‘before and after’ intervention study.

4.4.1.1 Eligibility criteria

The inclusion criteria shown in Table 4-2 and exclusion criteria shown in Table 4-3 define the study sample.

Table 4-2 Inclusion criteria for study participants

Inclusion criteria	Rationale
Current patient on stroke rehabilitation ward	Study conducted on one research ward only
65 years or older	The study sample was a subsample of the stroke population admitted to the ward. The study sample only included older adults, defined as those aged 65 years or older (Public Health England 2019b), which was a requirement of the funder for this study.
Patient eating regular textured diet (regular foods, level 7 of international dysphagia diet standards initiative) (IDDSI Committee 2016)*	Foods provided on the finger food menu were only suitable for patients on level 7 regular diet. Not suitable for patients on recommended modified diet.

*Note: Level 7 of IDDSI standards, includes patients able to eat ‘solid, hard and adhesive (sticky) foods which require an increased chewing rate, longer chewing duration and greater muscle effort’ (IDDSI Committee 2016).

Table 4-3 Exclusion criteria for study participants

Exclusion criteria	Rationale
On the end-of-life care pathway	Likely to have other implications that impact on eating and drinking
Partial or full enteral feeding	Unlikely to be able to engage in eating process
Unable to give consent and no consultee able to consent on behalf of patient.	Unable to provide appropriate consent to the study
In a side room on the ward	Unable to undertake observations
Significant food allergies, intolerances or other dietary restrictions that could not be catered for by the finger food menu.	Finger food menu limited during study

All patients were eligible to participate irrespective of their social, racial, or ethnic background. The study budget was not sufficient to employ an interpreter to support recruitment. Therefore, only participants who could communicate in English were recruited.

Participants were included in the study if they met the eligibility criteria displayed in Table 4-2. The eligibility criteria did not include participants deemed to be at risk of malnutrition or those who had undertaken an eating disability assessment. Patients were eligible to participate regardless of their risk of malnutrition as measured by the Malnutrition Universal Screening Tool (MUST) tool (BAPEN 2016). Normal practice within the clinical setting was to use the MUST to screen for malnutrition risk. This tool uses weight, weight loss and disease state as malnutrition risk. It identifies those at risk of malnutrition so clinical nutritional interventions can be implemented as required. Similarly, an eating disability assessment identifies those who may require a specific intervention to support nutritional status and safe provision of nutrition. This study focused on providing foods to a participant group who did not necessarily require clinical nutrition interventions or interventions to support an eating disability.

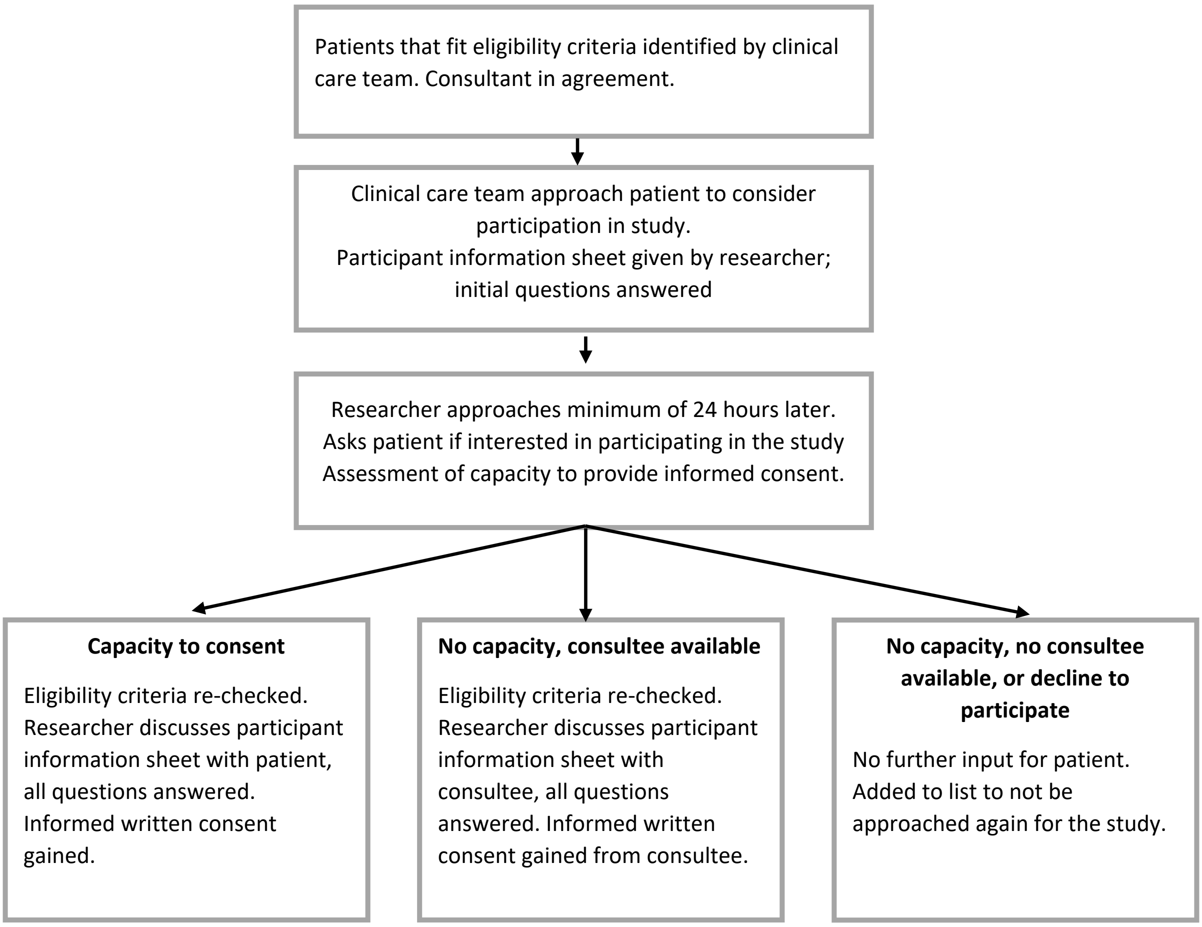
4.4.1.2 **Setting and location**

Patients for this study were recruited from a stroke rehabilitation ward at an NHS teaching hospital site on the south coast of England. The ward received patients from the hyper-acute stroke team within the hospital who provided a rapid stroke assessment service 24 hours a day to ensure all stroke patients were assessed and managed by the specialist team as soon as possible after admission. The ward aimed to assess the patients' type of stroke using computerised tomography (CT) imaging, investigate the cause of stroke, commence medication to reduce further brain damage and assess needs and develop rehabilitation goals. Rehabilitation started on the ward when patients were deemed medically stable and plans regarding continued care discussed with the patient and significant others. The ward was supported by dedicated consultants, doctors, nursing staff and therapy teams, including SLTs and Dietitians.

The stroke ward contained 28 beds, with a mean rate of admission at 36 patients per month (between January 2018 and June 2018). The ward was designed in bays, with four bays consisting of six beds and four side rooms. Bays were allocated by gender and levels of rehabilitation support required. Typically, side rooms admitted infectious patients. As per Table 4-3, patients in side rooms were not eligible for the study.

4.4.1.3 **Identification of participants and recruitment**

The recruitment process is summarised in Figure 4-1. A poster (shown in Appendix H) was displayed on the study ward to inform patients and relatives of the study.



Patients that fit eligibility criteria identified by clinical care team. Consultant in agreement.

Clinical care team approach patient to consider participation in study.
Participant information sheet given by researcher; initial questions answered

Researcher approaches minimum of 24 hours later.
Asks patient if interested in participating in the study
Assessment of capacity to provide informed consent.

Capacity to consent

Eligibility criteria re-checked. Researcher discusses participant information sheet with patient, all questions answered. Informed written consent gained.

No capacity, consultee available

Eligibility criteria re-checked. Researcher discusses participant information sheet with consultee, all questions answered. Informed written consent gained from consultee.

No capacity, no consultee available, or decline to participate

No further input for patient. Added to list to not be approached again for the study.

Figure 4-1 Recruitment process for ‘before and after’ quantitative data collection and mealtime observations

4.4.1.4 Considerations and adjustments for consenting participants after stroke

The Health Research Authority (HRA) is the monitoring body that protects and promotes the interests of patients and public in health and social care research undertaken in the NHS. The HRA requires that legal and ethical valid informed consent must be:

- Given by someone with capacity
- Given voluntarily under no influence
- Given by someone who has been adequately informed and with a fair choice (Health Research Authority)

The Mental Capacity Act (MCA), 2005, underpins valid informed consent making for research trials not considered to be a Clinical Trial of an Investigational Medicinal Product (Health Research Authority (no date)). The MCA states that a person must be assumed to have capacity, unless it is established that he/she lacks capacity (UK Government 2005).

One third of people after stroke have aphasia or communication difficulties which can affect understanding, talking, reading and writing (NIHR 2018) and potentially impact on decision making. Obtaining valid informed consent from participants with potential for communication difficulties or aphasia was supported by the PhD candidate's clinical role as an SLT. This meant she had experience in supporting and undertaking assessment of mental capacity for specific decision making in clinical practice. The test for capacity is notoriously difficult to apply in practice, which often leads to inconsistencies in its performance. Research has shown that SLTs have skills to enhance the decision-making capability for people with aphasia (Suleman and Kim 2015; McCormick et al. 2017). In addition, prior to the data collection period the PhD candidate completed a 'valid informed consent' training course to support assessing mental capacity for research decisions.

Providing information to inform participants

The Mental Capacity Act, 2005 states that information about partaking in a research study must be provided in a way appropriate to a person's circumstances to support decision making (UK Government 2005). A patient information sheet (PIS) (Appendix I) provided potential participants with written information about the study to ensure they were fully informed. The PIS included the nature and purpose of the research, the risks, benefits and reasonable alternatives, information about how to withdraw and confidentiality and anonymity.

Alongside information from the participant information sheet, other modes of communicating this information were provided to ensure that patients were able to be fully informed to make decisions regarding their participation in the study. Informing the participant of what the study involved was part of ensuring that they were adequately informed (Health Research Authority). Aphasia-friendly participant information sheets shown in Appendix J, page 277 were produced to ensure that the written information about the study could be effectively understood by the target sample (Rose et al. 2011).

There are two important components to be considered prior to producing written health information for people with aphasia or communication difficulties, although individual preferences can also play a role (Rose et al. 2011). Firstly, the readability of a text and secondly design attributes such as typography and the inclusion of graphics (Rose et al. 2011).

Readability of text for people with aphasia

Readability is a measure to define the ease of reading the content and is based upon the writing style (Pothier et al. 2008). Reducing the readability level of text is a process that can be used to ensure that information is more accessible for people with aphasia (Aleligay et al. 2008). The

Flesch-Kincaid grade level test, a formula based on average word length and sentence length, is frequently used within health care to assess readability (Flesch 1948) and can be easily calculated using Microsoft Word. Patient information sheets for this study were designed with a low readability rating. For aphasia friendly participant information sheets, the Flesch-Kincaid readability rating was 3.9. To put this into context, a study by Aleligay et al. (2008) explored the readability levels of 84 written health care information texts produced for people with aphasia. The study showed that the mean Flesch-Kincaid readability rating for information reviewed was 9.3. Aleligay et al. (2008) considered texts with a low readability rating as those with a Flesch-Kincaid of five or below and showed that 90% of the texts reviewed were rated above the recommended readability level and likely that the information provided was too complex for people with aphasia.

Design attributes of text for people with aphasia

Rose et al. (2011) used a qualitative study to explore barriers and facilitators to formatting characteristics, for providing people with aphasia printed educational materials (Rose et al. 2011). The design characteristics (typography, layout, emphasis, document type, colour and graphics) described by Rose et al. (2011) (Table 4-4) were used to create the aphasia friendly participant information sheet shown in Appendix J, page 277 .

Table 4-4 Facilitators to supporting design of aphasia friendly health education texts (Rose et al. 2011)

Category	**Facilitators to formatting**
Typography	Large print Thick print Sans serif font
Layout	Bullet points Spaced out information Headings
Emphasis	Bold text Headings that link to content
Document type	Larger page type
Colour	Black text on white background Coloured sections
Graphics	Inclusion of graphics, which are not ambiguous

Information from best practice guidelines ‘Accessible information guidelines’ (The Stroke Association 2012) and ‘Resources for stroke researchers’ (NIHR 2018) were also used to support the design of research documents for people with aphasia. These guidelines are based upon consensus of groups of people with aphasia and SLTs and suggest that short messages, clear sentences, easy words, a good layout with a consistent font, message layout and graphics improve readability.

Involvement of a personal consultee

In this feasibility study, participants were deemed unable to consent to the study if they were unable to show understanding of the information relevant to the decision, retain relevant information, use or weigh up information regarding the decision and communicate their decision (UK Government 2005). In these circumstances, The Mental Capacity Act states the research should 'take reasonable steps' to locate a personal consultee. Personal consultees are defined as 'someone who knows the person and is able to advise the researcher regarding the persons wishes and feelings in relation to the project and whether they should take part' (Department of Health Scientific Development and Bioethics Division 2008 p. 3). Although this guidance can be deemed ambiguous for some and lead to interpretation, it provides flexibility in allowing the researcher to rationally and practically ensure that participation in the research is not limited (Heywood et al. 2019). For this feasibility study, an information sheet was designed to give to personal consultees information about the study (shown in Appendix K) and written consent was required from consultees. The PhD candidate was responsible for allocating a personal consultee to provide written consent.

The possibility of fluctuating capacity following a stroke in the acute stage of care was acknowledged. Where a participant consented to take part in the research and then lost capacity, a discussion with a consultee was sought to advise whether the participant should continue to participate in the research.

4.4.1.5 **Sample size**

The primary aim of this study was to assess feasibility meaning a power calculation was not required. A sample size of 30 participants is used as a general rule within preliminary studies to provide adequate data collection (Browne 1995; Lancaster et al. 2004). The sample size of 31 participants was predetermined and considered sufficient to meet the objectives of collecting data on outcome measure variation, recruitment, and retention. This was also a pragmatic decision based upon the PhD candidate's time availability and limitations to funding.

Recruitment to the study ran from January 2019 to September 2019, and it was estimated that approximately four participants a month would be recruited. Data could only be collected for a maximum of two participants per week to provide opportunity for the lone PhD candidate to conduct mealtime observations over three lunchtime meals.

4.4.2 Participants involved in semi-structured interviews

Interviews were conducted with 12 patient participants who were observed over lunchtime meals in the first phase of the study and 11 members of staff involved in mealtimes on the study ward. This section highlights key details relating to the eligibility criteria, setting and identification of patients and staff for inclusion in interviews.

4.4.2.1 Eligibility criteria

Inclusion and exclusion criteria are displayed in Table 4-5.

Table 4-5 Inclusion and exclusion criteria for patient and staff interviews

	Inclusion criteria	Exclusion criteria	Rationale
Semi structured interviews with patients	Patients with capacity to consent to research study. Reliable means of communicating.	N/A	Ensure participants were not under additional stress when undertaking interviews.
Semi structured interviews with staff	Any paid member of staff employed to work on the study ward with direct involvement with lunchtime mealtimes on the study ward.	Unable to converse ideas in English language.	Ensure that members of staff have been involved in the feasibility study and can reflect on experiences. Ensure that the PhD candidate could communicate with the member of staff.

4.4.2.2 Identification of participants and recruitment

A summary of key details with regards to identification of participants for interview recruitment are displayed in Table 4-6.

Table 4-6 Table summarising interview parameters for interviews with patients and staff

	Recruitment	Sampling	Criteria for sampling
Semi structured interviews with patients	Participants asked to take part in the interview after they have been observed in phase 1.	Purposeful	Gender Age – below 80 and above 80 Number of finger food meals trialled
Semi structured interviews with staff	Staff recruitment poster on ward (Appendix L) Reimbursed with voucher	Purposeful Snowball	Profession

For patients, a purposefully selected sample of participants observed during the 'before and after' study was interviewed to best help explain the quantitative results. The purposeful sampling strategy for patient participants was based on gender, age, and number of finger food meals trialled. Participation in the interview phase was outlined in the participant information sheet and discussed with the participant on consent. Participants were required to opt into taking part in an interview on consent forms (see Appendix M, page 285).

For staff, a purposeful sampling strategy was used based upon staff profession and pay grade (Ritchie et al. 2012). Staff were recruited for interviews following the recruitment flow chart in Figure 4-2. Any member of staff who was involved with mealtimes on the stroke rehabilitation ward was eligible to participate. This included ward and catering staff to enable a wide variety of views to be collected. Ward staff were provided with written information sheet (Appendix N) and written consent was gained using a form displayed in Appendix O.

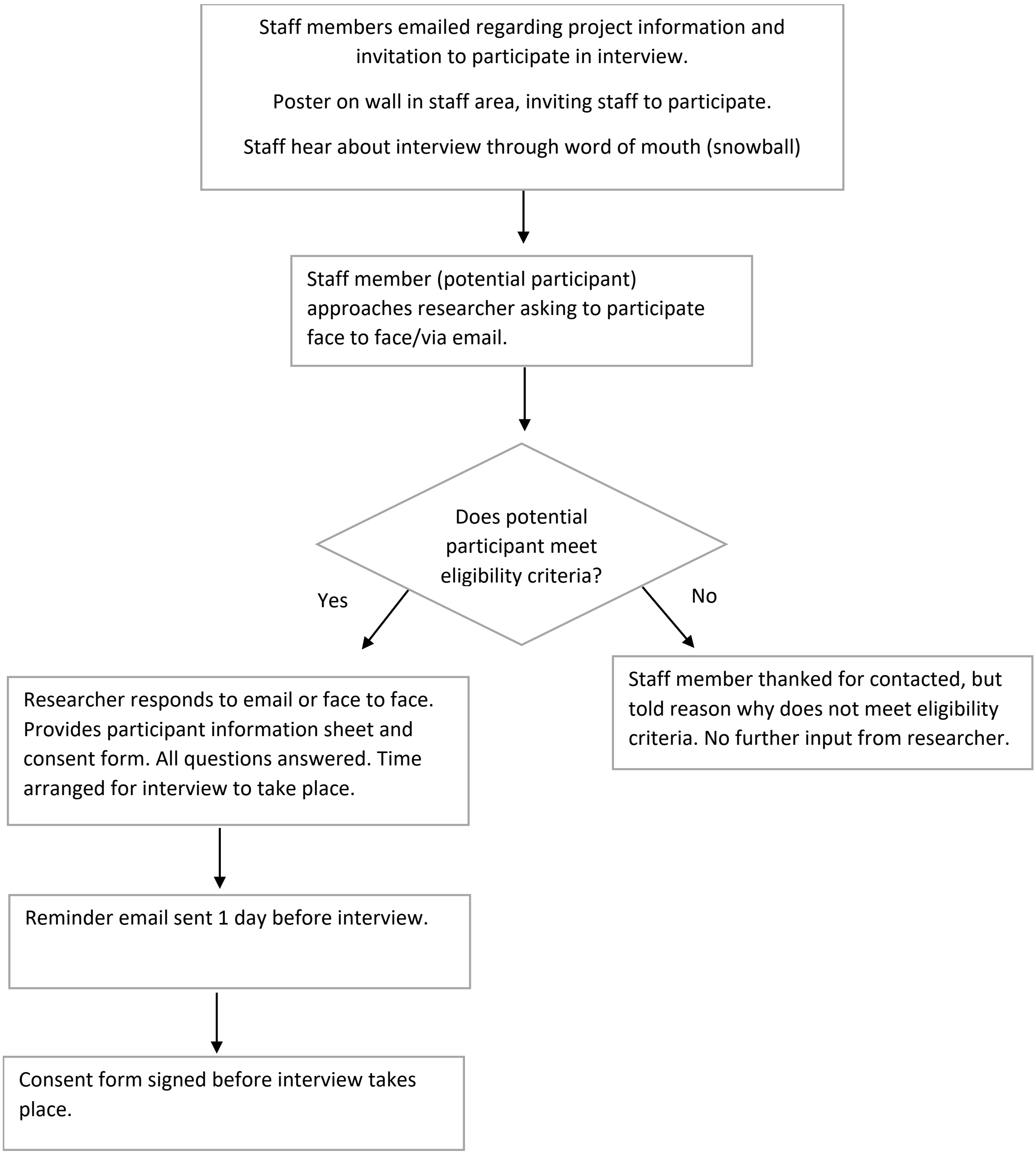


Figure 4-2 Recruitment process for staff interviews

4.4.2.3 Sample size for interviews

Interviews with a maximum of 12 patients and 12 members of staff was deemed pragmatic for the study and in line with previous qualitative studies (Watkins et al. 2017). Typically, in qualitative research, smaller sample sizes are used to explore phenomena in depth and detail rather than to statistically represent the general population (Ritchie et al. 2012). Purposeful sampling was used, which involved the intentional selection of participants to take part in the research who have experienced the key concept being studied (Creswell and Plano Clark 2018). For this study, all staff interviewed were involved in mealtimes on the stroke rehabilitation ward and had been sampled due to their involvement in the implementation of the finger food menu. Patient participants interviewed had consented to trial the finger food menu.

4.5 Intervention

During the 'before and after' study design, participants acted as their own control receiving the standard 'à -la carte' menu offered at the hospital site at lunchtime on day one of the study and offered the finger food menu over two following lunchtime meals. Study timings are displayed in Figure 4-3.

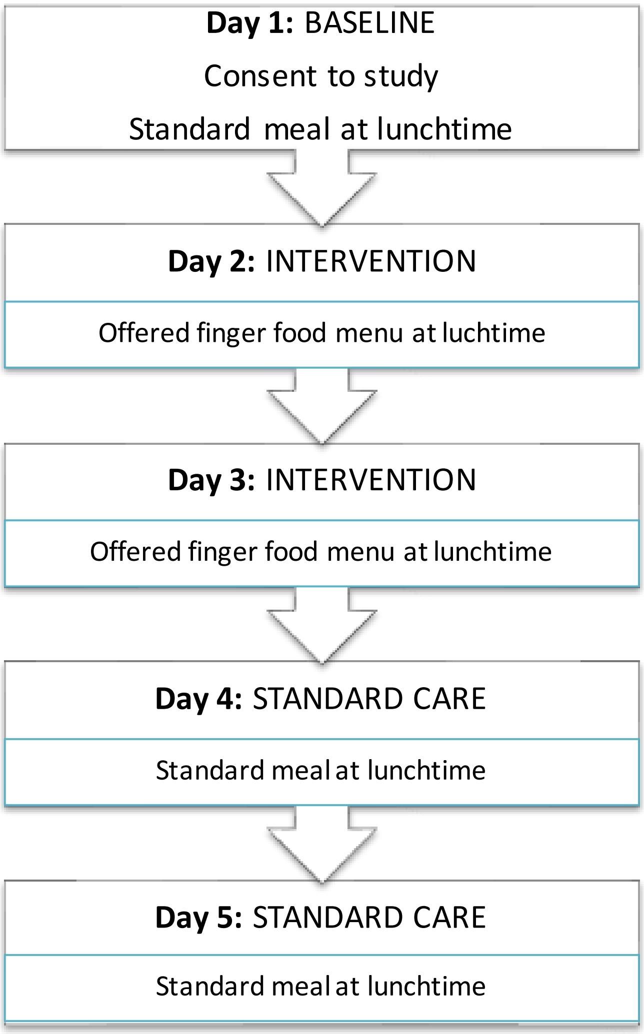


Figure 4-3 Process flow chart illustrating the stages of the study.

Participants were included in the study for a maximum of seven days. Most participants completed the study within the first three days of consent. However, allowing participants in the study for up to seven days provided flexibility with data collection within the complex and changing hospital environment. Enrolment in the study for seven days was deemed pragmatic, considering previous hospital nutrition studies reported that follow up periods of 14 days produced high attrition rates (Collins et al. 2017b). In circumstances where the PhD candidate could not collect data from day one or day two of the study, but the participant continued to meet eligibility criteria, the participant was approached during further days of data collection to ask if they still wanted to be involved with the study.

For both intervention and baseline periods, the template for intervention description and replication (TIDieR) checklist was used to ensure adequate reporting and transparency (Hoffmann et al. 2014). This checklist includes 12 points (shown in Table 4-7) and is recommended for use in nutritional intervention studies by Herke et al. (2018) to support comparison and critique of different studies.

As per Figure 4-3, day one in the study acted as the baseline measure. Participants received standard care, selecting, and eating a lunchtime meal from the standard á-la carte menu.

Table 4-7 TIDieR checklist for standard meal and finger food intervention meal

TIDieR checklist item	Details for standard meal (day 1)	Details for finger food meal (day 2 and day 3)
Why	• The baseline period was 'standard care' used to provide a comparison between the standard menu and finger food menu intervention and provided contextual information. • One baseline measure was considered appropriate due to limited variability recorded in dietary intake across participants (Roberts et al. 2017).	• The finger food menu intervention was offered to people after stroke, one group at particular risk of eating difficulties, malnutrition and poor outcomes (Burgos et al. 2018). • People in hospital post stroke typically have long hospital admissions in which they undergo an intense rehabilitation programme. • It is important that they are provided with a varied menu to avoid menu fatigue (British Dietetic Association 2017) and are supported to successfully participate in a mealtime. • There have been limited studies evaluating the use of finger foods with people with stroke, and therefore warrants full assessment of feasibility for the use of finger foods for this client group
Materials	• Participants were offered food from the standard hospital food menu. • The menu included a selection of hot and cold items as a main meal and dessert. • Items were presented on a text printed menu or a photo menu.	• Development and design of the finger food menu is fully defined in Chapter 3. • During the intervention period, participants were offered to choose menu items from the printed finger food menu designed for this study, presented in Figure 3-3 and Figure 3-4 (page 91).
Procedure	• The ward host employed by the external catering company was	• Each morning of the intervention period, the PhD candidate offered

TIDieR checklist item	Details for standard meal (day 1)	Details for finger food meal (day 2 and day 3)
	responsible for taking orders during the 'standard meal'. • The PhD candidate was on the ward over lunchtime when meals were delivered to determine whether menu items were delivered as intended.	participants choices from the finger food menu. • Any orders made from the menu were passed onto the catering team. • The PhD candidate was on the ward over lunchtime when meals were delivered to determine whether menu items were delivered as intended.
Who provided	• Orders taken by ward host on study ward as per usual care. The ward host delivered and collected meal trays.	• The PhD candidate was on the study ward during ordering to explain the finger food menu. The ward host delivered and collected meal trays.
How	• The PhD candidate was not present during ordering. Ward staff provided the food chosen over lunchtime. • The provision of staff support during mealtimes was not changed. Over lunchtime, the PhD candidate undertook non-participant observations.	• The PhD candidate attended the study ward and offered participants to order from the finger food menu. This involved face-to-face interaction. • Ward staff provided the food chosen over lunchtime. • The provision of staff support during mealtimes was not changed. Over lunchtime, the PhD candidate undertook non-participant observations.
Where:	• Stroke rehabilitation ward, NHS Trust, South England	• Stroke rehabilitation ward, NHS Trust, South England
When and how much:	• Participants offered standard menu for one day during the study trial.	• Participants were offered to trial the finger food menu for two lunchtime meals.
Tailoring	• None reported	• Participants were offered to choose items form the newly designed finger food menu during mealtime observations on day two and day three. • Participants were not obliged to choose from the finger food menu and on request were able to choose items from the standard menu during observations on day two and three. This was recorded by the PhD candidate.
Modifications	• None reported	• Two items were removed from the finger food menu as they were unable to be sourced by the hospital Trust during the study.
How well	• None reported	• Fidelity was assessed using mealtime observations. The PhD candidate was on the ward during meal ordering and over lunchtimes of interest to support intervention adherence.

4.6 Data collection

4.6.1 Participant characteristic data collection

Information regarding participant characteristics was collected from medical records using a form designed and piloted by the PhD candidate presented in Appendix P. The information collected included gender, age, length of stay (from admission to consent to study), BMI on admission, MUST score on admission, evidence of input from a dietitian during the inpatient stay, NIH Stroke Scale score on admission (National Institute of Neurological Disorders and Stroke) and any evidence of cognitive impairment. The rationale for collecting this data as part of the feasibility study was to distinguish the suitability of data, to support understanding the sample recruited, and to acknowledge ease of data collection methods.

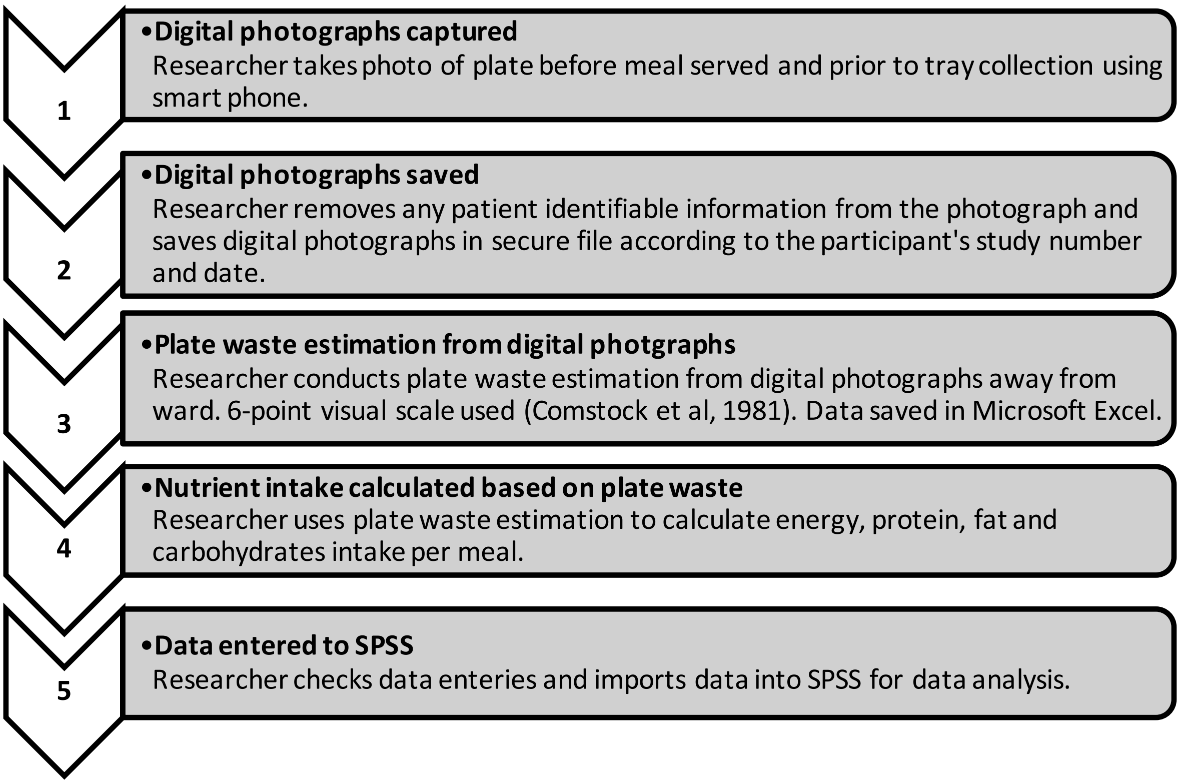
4.6.2 Dietary intake data collection

Dietary intake (energy, protein, carbohydrate and fat) was recorded for participants across three lunchtime meals. This was recorded using a measure of plate waste from a digital image taken pre meal delivery and post meal consumption. This method has successfully been used in hospital settings (Ofei et al. 2015). It is described as reducing disruption of mealtime service on a busy hospital ward (Williamson et al. 2003) and allows visual estimation of plate waste from a digital image to be performed away from the food service area and therefore in a less hurried environment (Navarro et al. 2014). One of the main aims of this feasibility study was to assess the suitability and inter-rater reliability for using this outcome measure to estimate energy, protein, fat and carbohydrate intake and using digital images also allowed for inter-rater reliability testing away from the ward.

Using digital images was chosen over other strategies which rely on direct visual estimation of plate waste on the ward (Williamson et al. 2003) or weighing of plate waste (Roberts et al. 2013). Direct visual estimates of food portion to calculate plate waste provide good approximates to levels of food waste, but estimates are often rushed or missed on a busy ward (Williamson et al. 2003). Weighing methods can accurately assess plate waste but involve collecting the weights of each food component which can be challenging to implement within a busy ward environment without interrupting normal foodservice and requires significant resources and time (Williams and Walton 2011).

Due to the short duration of the feasibility study, nutritional status was not used as an outcome measure. Nutritional status is typically reported as either a change in nutrition status using MUST score or equivalent or change in weight. For a stable nutritional status score, follow up scores need to be at least 16 weeks from the baseline (Herke et al. 2018), which is not practical to assess for a hospital inpatient stay unless the participant was followed up in the community.

Figure 4-4 shows a summarised process map of data collection to calculate dietary intake.



1 **•Digital photographs captured**
Researcher takes photo of plate before meal served and prior to tray collection using smart phone.

2 **•Digital photographs saved**
Researcher removes any patient identifiable information from the photograph and saves digital photographs in secure file according to the participant's study number and date.

3 **•Plate waste estimation from digital photgraphs**
Researcher conducts plate waste estimation from digital photographs away from ward. 6-point visual scale used (Comstock et al, 1981). Data saved in Microsoft Excel.

4 **•Nutrient intake calculated based on plate waste**
Researcher uses plate waste estimation to calculate energy, protein, fat and carbohydrates intake per meal.

5 **•Data entered to SPSS**
Researcher checks data enteries and imports data into SPSS for data analysis.

Figure 4-4 Process map of dietary intake data collection

4.6.2.1 Plate waste from digital photographs

Plate waste is defined as the food provided but not consumed by the patient. It is an important measure of food consumption and used to define dietary intake (Valero Díaz and Caracuel García 2013; British Dietetic Association 2017).

To visually estimate plate waste, a six-point scale, as described by Comstock et al. (1981) was used. The scale uses six points to determine what proportion of food has been eaten. The points on the scale range from all eaten, one bite eaten, three quarters eaten, half-eaten, one quarter eaten to none eaten (Comstock et al. 1981). This scale has been widely used to measure plate waste in different settings (Williamson et al. 2003; Swanson 2008). Waste from each food item on the plate was separately estimated.

4.6.2.2 Calculation of nutrient intake

Nutrient intake was calculated for lunchtime meals for individual participants. Food composition data were obtained from the hospital caterer. This was emailed to the researcher in the form of an electronic spreadsheet containing the nutritional composition (energy, protein, fat and carbohydrate) of all foods supplied on the hospital standard menu and finger food menu. All food items were served using standard portion sizes. This study did not record micronutrient intake of menu items. Nutrient intake was calculated from the percentage of each food item consumed (inverse of plate waste), multiplied by its nutrient composition (energy, protein, fat and carbohydrate) and summed.

E.g., On day 2 where the finger food menu was offered, patient 003 ate 50% of a sausage roll (191kcal, 5g protein, 12g fat, 15g carbohydrate) and 100% of cheese and crackers portion (236kcal, 11g protein, 16g fat, 10g carbohydrate). This equated to overall nutrient intake of 427kcal, 16g protein, 28g fat and 25g carbohydrate.

This method has been trialled and reported in a study to calculate nutritional intake on a hospital ward (Roberts et al. 2013).

4.6.2.3 **Inter-rater reliability of plate waste**

To assess inter-rater reliability of plate waste estimation, the PhD candidate (researcher 1) and a SLT student (researcher 2) independently estimated plate waste from each item of food (275 items) from the digital photographs. The student SLT was provided with written information about how to conduct the ratings, described as a guide to estimating food intake shown in Appendix Q. To reduce bias, the main aim of the study was not disclosed, and plate waste estimates were analysed independently.

4.6.2.4 **Intervention costs**

Intervention costs for this study were based on micro costing, or bottom-up costing, of setting up and delivering the intervention. Micro costing attempts to measure the costs of a service as accurately as possible by studying the costs of individual elements (Edwards and McIntosh 2019a). Costs were evaluated based on the data collection period between January 2019 to September 2019. All costs were reported in pound sterling and based on costs retrieved during 2019.

Direct and indirect costs were discussed and agreed upon with the catering manager during the intervention development stage as displayed in Table 3-4, page 93 and were based on activities that occurred during the feasibility trial. Although a range of indirect and direct costs was identified, from the catering provider, hospital provider, and family perspective, food costs were the only direct costs that could be monetised based on the activities included in this feasibility study. Monetary value could not be allocated to other direct or indirect costs including production and printing of the additional menu, time required for ward hosts to prepare the finger food meal trays, staff training, staff costs to support mealtimes, food provision provided by family. Other than food costs, items were listed as costs that organisations may need to consider for a future trial.

To calculate direct food costs, prices of individual menu items were provided by the catering team at the hospital Trust. The information was presented in an excel spreadsheet displaying:

- A list of menu items from the standard al la carte menu
- A list of menu items offered as part of the finger food menu
- The corresponding supplier for each menu item
- The cost of each menu item for an individual portion.

To assess the cost difference between the standard menu and the finger food menu during the feasibility study, the PhD candidate recorded which menu items each participant ordered. The costs of the menu items chosen were aggregated. The mean cost of the standard menu and the finger food menu items were then calculated and compared. Table 4-8 provides an example of food item costs from one participants order.

Table 4-8 Example costs of standard and finger food menu items

Standard menu item	**Cost per portion (£)**	**Finger food menu item**	**Cost per portion (£)**
Fish in cheese sauce	0.86	Pizza	0.67
Mashed potato	0.36	Carrots	0.18
Mashed swede	0.28	Cheese and crackers	0.20
Ice cream	0.09		
Total meal cost (£)	**1.59**		**1.05**

4.6.3 Fieldnotes from mealtime observations

Direct, non-participant mealtime observations generated data to capture actions and behaviours of participants (Durdella 2017), a central aspect to all real-world research (Robson and McCartan 2016). Observations allowed the PhD candidate to understand how the intervention was delivered on the ward and what needed to be adapted to make it feasible to be used on different wards in a future larger study. Fieldnotes from observations were analysed to better understand factors that influenced implementation. Patient's underestimate eating difficulties when compared with objective measures (Elmståhl et al. 1999), therefore observing mealtimes allowed the collection of first-hand data of eating, complemented by patient interviews in the second phase. Observations have been widely used in mealtime studies to observe mealtime culture and to support further data from participants with cognitive impairment or communication difficulties who may not be able to participate in an interview.

Mealtime observations coincided with the usual timings of mealtimes on the ward, occurring between 12pm to 2:30pm. During the observations, the PhD candidate sat within the ward bay or at the door, with a clear view of the participants. She attempted to be out of sight of the participant during observations, avoiding eye contact where possible and having minimal interaction. The PhD candidate did not interact with the participant during the observation. Observations were overt, meaning participants and staff were aware of the researcher's presence and the research aims. The prolonged duration of data collection allowed staff to become accustomed to the PhD candidate's presence.

An observation schedule, developed and piloted by the PhD candidate, prompted the recording of specific data including: timing of the meal (time meal tray served, time participant started eating, time participant stopped eating); number of patients in the bay; staffing levels; events occurring at mealtimes such as radio or television being on; nature of interactions with ward staff, relatives, visitors or other patients; contextual data, including a sketch of bay and position of participants and researcher. The sketch of the bay was used to support recall for the PhD candidate during thematic analysis of field note data. An example of this is shown in Appendix R.

4.6.4 Semi structured interviews

Semi structured interviews were used to record experiences of patients and staff of using finger foods on the acute stroke ward and to explain and expand on results from the 'before and after' intervention study. Semi-structured interviews provided a standardised approach to face-to-face discussions, using predetermined open and probing questions. This allowed focused flexibility and exploration of topics in more depth (Legard et al. 2012).

Face-to-face interviews were chosen as a pragmatic approach rather than focus groups for interviewing participants who were patients (Lewis and Nicholls 2013). Focus groups were not deemed ethical to use with a group of patients with potential language difficulties resulting from their stroke. Enabling techniques provided guidance to how realistic and honest opinions were supported during interviews, which may have otherwise been naturally occurring within focus groups (Kitzinger 2006).

Face-to-face interviews were chosen to record the experiences and views of participants who were staff involved in the study regarding the use of finger foods. Face to face interviews were elected over focus groups as recruitment to focus groups were considered a challenge for busy members of staff who are working within the same clinical area. These challenges were highlighted in a feasibility study by Collins et al. (2017a) where the inability to schedule meetings with all staff participants at the same time required an alteration to methods.

All interviews were audio recorded to obtain verbatim speech with full details of dialect and pauses (Arthur et al. 2014). This allowed the PhD candidate to pay full attention to the interview itself and focus on responding directly to participants' comments (Arthur et al. 2014). Contextual field notes were taken before and after the interview to document key points from the discussion and to record any actions or events of note during the interview (Arthur et al. 2014). Field notes were recorded as informal jottings. These were not used in the data analysis but were used to help to contextualise the data during data transcription and analysis.

A topic guide, developed by the PhD candidate, provided support to steer the discussion and encourage consistency between interviews. The guide included a level of flexibility to allow the PhD candidate to expand on information provided by the participant, explore topics captured in observations and previous interviews (Arthur et al. 2014). A separate topic guide was developed and used for patient and staff interviews shown in Appendix S.

Topic guides were developed based on the research question. A list of potential topics to further explore within the interviews was established, based on domains (mealtime experience, meal access, and meal quality) described by Keller et al. (2014). From these topics, a series of potential questions were drafted and cross-checked to ensure they related to the research question. Questions were refined and organised into a list. The topic guide was piloted with the PhD candidate's clinical colleagues to ensure that concepts could be understood, and the questions had a good flow. Clinical colleagues gave comments to clarify the wording of questions and encouraged using digital photos of the food to elicit discussion. Based on these comments, the topic guide was refined.

The topic guide initially provided a short introductory period to set the context for the interview, facilitate rapport building and reaffirm anonymity. Initially, a short descriptive question was asked to help them feel at ease and to recognise the conversational style of the interview (Arthur et al. 2014). Questions in the main interview body were based on the mealtime intervention conceptual model by Keller et al. (2014) described in section 1.7, page 33, including questions regarding mealtime experience, access, and meal quality and based on results from quantitative data collection. Within the main body, probing questions were incorporated into the topic guide to encourage the participant to expand on responses and summarise questions to help the researcher clarify points made. At the end of the interview the PhD candidate thanked the participant and provided members of staff with a voucher to reimburse them for their time.

Enabling techniques were used throughout the interviews to facilitate participants to discuss their views more deeply and to encourage further thinking (Arthur et al. 2014). Digital photographs taken during phase 1 of the study (the most recent finger food meal) were shown to patients to support recall and to remain on task. A selection of six digital photographs taken during phase 1 of the study were shown to staff interviewed to support recall of ideas. During interviews the researcher provided ‘permission’ to report negative views using questions like: “Sometimes people find X difficult, what about you?”

4.6.4.1 **Setting and location**

Participants who were patients were interviewed as soon as possible after the lunchtime meal to reduce recall bias (where participants do not accurately remember previous events or experiences). Interviews took place at the participants bedsides. Conducting interviews at the bedside meant that it was convenient for participants who were patients to take part and that nursing staff were in proximity in case of acute deterioration. Disadvantages to undertaking interviews on the ward included noisy environment with possible interruptions. Participants were offered to be interviewed away from the bedside and this was at the patient’s discretion.

At the time of data collection, the PhD candidate did not have a clinical role on the ward. This meant she was not involved with any care of the participants or patients on the study ward but was familiar with members of the staff from her previous clinical role. During data collection, the PhD candidate clearly displayed her university badge and only participated in research activities. The researcher’s role was made clear to ward staff and she requested that any clinical questions were re-directed to clinical SLT working on the ward.

Interviews with staff took place in a research room away from the study ward. Confidentiality was maintained by closing the door and using a sign requesting others not to disturb. Staff were offered a drink on arrival to help them to feel at ease. Staff arranged a time outside of working hours with the PhD candidate for the interviews to take place, typically after a clinical shift on the ward as detailed on the ethics application. Interviews with staff lasted up to 60 minutes. Staff were provided with a voucher to reimburse them for their time.

4.7 Pre-specified criteria to judge whether to proceed with future definitive trial

The criteria for success of a feasibility study should be based upon the primary feasibility objectives, which allow interpretations to be made regarding whether to proceed with a future trial (Thabane et al. 2010). An assessment regarding the viability of a future definitive trial should be made (Williams 2016), in which commonly a traffic light system is used to judge criteria (e.g., recruitment below a certain level the trial is not feasible, above a certain level the trial is feasible and between the two the trail is feasible if appropriate changes are made (Eldridge et al. 2016a)).

Assessment of a future study against several pre-specified criteria informs the study design and intervention for use in a wider context (Hallingberg et al. 2018). Typically, pre-specified assessment criteria consider the sample size, ability to meet recruitment targets, costings and support required to run a main trial (Hallingberg et al. 2018). Avery et al. (2017) have reported tips to develop criteria for progression onto the next stage of a study and suggests that assessment of trial recruitment, protocol adherence and outcome data should be conducted.

Findings from this feasibility study provided foundations for a future full evaluation of a finger food menu in hospitals. This study was viewed as feasible to proceed to a definitive trial if the following success criteria were met:

- Recruitment rate into the trial reaches an average of four patients a month
- Data were collected for 75% of participants during day 3 of the trial
- Food intake measurements are feasible and reliable measurement to use on the ward and therefore determined as suitable outcome measure
- Qualitative findings show finger foods can be successfully delivered and patients and staff generally report positive views regarding using finger foods
- Costs to using the finger food menu are relevant to the consequences.

The above criteria are reviewed based upon results from the study and used to determine future steps. The remainder of the chapter focuses on the intervention development for this feasibility study.

4.8 Blinding

Blinding is used to reduce bias by concealing participants' and/or researchers' knowledge of the intervention and/or baseline periods (Bowling 2014). In this feasibility study, it was not possible to blind participants or members of staff to whether the participant was on the baseline or intervention period, due to the nature of the intervention. It was also not possible to blind the PhD candidate during the data analysis period as the researcher had collected the data and was familiar with data collected from the small sample size of participants.

4.9 Randomisation

Participants in this feasibility study were not randomised. By not randomly assigning participants to groups, there was minimal disruption to the research setting (Dimitrov and Rumrill Jr 2003). Disadvantages of not randomising include threats to internal validity (Dimitrov and Rumrill Jr 2003), therefore caution is taken when describing results.

The study site had one stroke rehabilitation ward with ward bays allocated to patients based on gender and acuity of illness, which limited options for randomisation. Randomisation of participants using a crossover design was deemed more robust than pre-post design but impractical following the designs of other studies using a singular ward (Collins et al. 2017b). Using ward bays as a cluster control group was likely to cause variability between groups. Frequent patient moves or staff moving between bays was likely to increase risk of contamination and therefore not utilised.

4.10 Analytical methods

4.10.1 Quantitative data preparation and analysis

All quantitative data were double entered into Microsoft Excel to detect any data errors. Statistical analysis was conducted using SPSS statistics (version 26). Support for statistical analysis was provided by Valia Koutra (Senior Medical Statistician).

Participant characteristics were described using frequencies and percentages and presented separately for each day of data collected. Recruitment rates and retention were presented as percentages: recruitment rates were defined as the number of participants recruited to the study per month, retention rate was based on the number of patients consented for the study and number with fully completed outcome measures. The nature and reason of withdrawal or non-consent explained these results.

Analysis of inter-rater reliability was used to determine whether visual estimation of plate waste from digital photographs was a reliable method for multiple raters to use in a future study with a larger data set. The PhD candidate and a student SLT independently estimated plate waste based upon digital photographs. Data in SPSS were analysed using Cohen’s Kappa (κ) (Cohen 1960) to determine agreement between the PhD candidate and the student SLT's judgement of food plate waste. Cohens Kappa (K) coefficient can be used as a simple measure of agreement vs disagreements and remove the element of chance agreement or disagreement. Cohen's Kappa is appropriate to use as the study design meets the following assumptions:

- The response by the two raters is measured on a categorical scale
- Both raters assess the same observations
- Each response must have the same number of categories
- The two raters are independent
- The same two raters are used to judge all observations.

Descriptive statistics were used to describe data, comparing the standard meal with the intervention offered over two lunchtime meals. Descriptive data regarding energy, protein, fat and carbohydrate intake consumed across the three mealtimes of interest are presented. The median (middle value when all the data points are aligned in an ascending order), range and interquartile range of energy (kcal), protein (g), fat (g), and carbohydrate (g) consumed across each mealtime are displayed. Because of the small sample size, non-parametric tests were used to support description of the dietary intake data. Analysis took the form of Wilcoxon Signed Rank test to display the data.

4.10.2 Field note data preparation and analysis

4.10.2.1 **Data preparation**

The PhD candidate observed all baseline and intervention mealtimes using handwritten semi structured field notes as a first-hand record of the presentation and behaviours of participants at mealtimes. The handwritten field notes during the observation on the ward were transcribed onto a word document as soon as possible after the observation, as shown in Appendix R. This preserved the meaning of the notes. Field notes were time stamped and saved according to date, time and participant number and uploaded to NVivo 12 (QSR International 2020) for data analysis. Patient anonymity was maintained by using associated study identification numbers on notes.

4.10.2.2 **Rationale for using computer assisted software**

NVivo 12 software (QSR International 2020) supported data analysis by assisting with navigation and systematic searching of the data. It enabled the PhD candidate to remain grounded in raw data by providing easy navigation to and from codes and data sets and allowed flexibility to refine and add new ideas. It created a clear audit trail used to clearly discuss development in stages of analysis with the supervisory team (Snape and Spencer 2012). It is important to note that using computer technology to support the handling of data does not impede the crucial role of the researcher in the analysis process (Snape and Spencer 2012) and the researcher continued to generate themes from the data.

4.10.2.3 **Analysis of field note data**

Framework analysis, a matrix-based method for ordering and synthesising data, was used to analyse field notes on NVivo 12 (Ritchie et al. 2003). A central component to this method includes use of a 'thematic framework' to systematically organise data by key themes and concepts. Framework analysis is described as a pragmatic approach to qualitative analysis which can be used to address a specific research question (Ward et al. 2013). It acknowledges that the analysis may be shaped by pre-existing ideas and is less focused on producing a theory. Considering this, the framework was developed based on pre-existing concepts described by Keller et al. (2014) (first introduced in section 1.7).

The following steps to data analysis described by Ritchie et al. (2003) were followed.

1. **Familiarisation through immersion in the data** – The PhD candidate became familiar with the data by reading all field note data sets. This process allowed the PhD candidate to immerse herself in detail recorded in field notes and provide an overview of the data. All field notes were reviewed during the familiarisation process as the sample size was small enough to be studied. The familiarisation process was an active phase where recurring themes or ideas were identified and documented. A second researcher interested in qualitative analysis and hospital mealtimes read a random sample of 10 field notes and noted recurrent themes or concepts. The PhD candidate undertaking the review was ultimately responsible for the final themes; however, discussions between the two researchers allowed ideas to be developed.
2. **Developing a framework by identifying recurrent and important themes** – The themes documented were sorted and grouped under two domains relating to '*how* finger foods were used' and future recommendations to 'develop the intervention' to aid the organisation. Themes under the domain '*how* finger foods were used' were based on concepts described in the theoretical model by Keller et al. (2014). The model by Keller et al. (2014) was considered the most appropriate model to use as it encapsulated multiple inter-related and multi-level components that impact eating and was developed to guide the development and evaluation of complex mealtime interventions which considered the multi-level components. Themes relating to the 'development of the intervention' related to future recommendations to develop the

intervention. Based on the recurring themes documented and domains described by Keller et al. (2014), a framework was devised.

3. **Labelling the data** – Next, the data were systematically 'indexed' using the draft framework. This process involved re-reading datasets and noting where the essence of the data related to a theme on the framework. ‘Nodes’ representing themes were created on NVivo, acting as a filing system. Whenever a theme or concept was identified within the raw data set, the raw data were highlighted and ‘indexed’ under the ‘node’. This stage allowed the PhD candidate to be more immersed in the data and refine themes. The draft framework was revised to accurately reflect the data.
4. **Summarising and sorting the data** – NVivo was then used to create a visual matrix with the key themes listed across the top of the chart and corresponding data from each participant observation listed below. The PhD candidate reduced the data listed into understandable but brief summaries. The visual matrix allowed each theme to be systematically reviewed across cases.
5. **Synthesising the data** – The final step of the process involved synthesising the original data. This allowed for checking back from themes and subthemes against fieldnote data to ensure the essence of the raw data remained. No changes were made to the themes or sub-themes at this stage.

4.10.3 Semi structures interview data preparation and analysis

4.10.3.1 Data preparation

All semi-structured interviews were audio recorded. The PhD candidate transcribed all patient interviews and five staff interviews to facilitate familiarisation with the text. Due to time restraints, a university-approved transcriber was used to transcribe six staff interviews, which were longer in duration. Transcripts were added to NVivo12 (QSR International 2020), a data analysis software tool, to support data management. A template was used by the PhD candidate to ensure that each data source could be easily identified and linked to the appropriate participant in NVivo 12. A ‘case’ node in NVivo 12 was used (Woolf and Silver 2017) to preserve anonymity (QSR International 2020). Figure 4-5 presents steps involved in turning audio data into a transcribed document which is uploaded to the data analysis software.

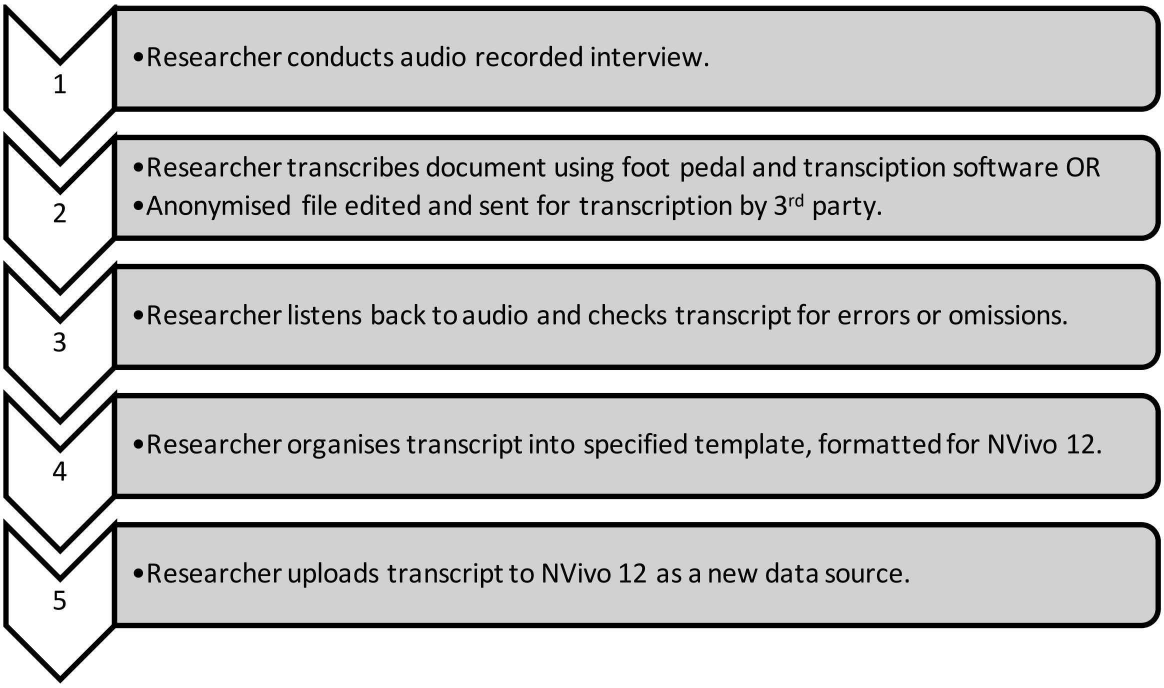


Figure 4-5 Qualitative interview data handling process

4.10.3.2 Thematic analysis of qualitative interview data

Thematic analysis was used to identify patterns and themes across interview transcripts and was used to describe the relationship between participant views and experiences (Braun and Clarke 2006). An inductive approach was used in which codes and themes were developed through the content of the data. The stages outlined by Braun and Clarke (2006) shown in Figure 4-6 were employed. The arrow between steps is representative of the iterative process and movement between steps encouraged by Braun and Clarke (2006).

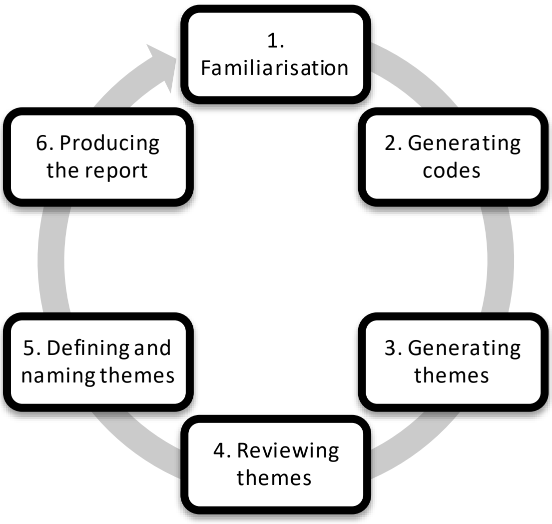


Figure 4-6 Iterative process to thematic analysis Braun and Clarke (2006)

Step 1 – Familiarisation

Familiarisation involved the PhD candidate immersing herself in the data, becoming familiar with the content of the data collected (Braun and Clarke 2013). The PhD candidate collected all data for this research study; therefore, the familiarisation stage was ingrained during the data collection stage. The familiarisation phase was an active process (Braun and Clarke 2013) involving re-reading through field notes, keeping notes on initial points of interest, reflections on what has been seen and reflections on what assumptions are being made. These were revisited during the following phases as part of the iterative approach.

Step 2 – Generating codes

Data were searched line by line to look for elements of interest in relation to the research questions (Braun and Clarke 2013) and captured using 'codes' (succinct labels that identify notable features of data, important in answering the research question (Braun and Clarke 2006)). Codes and accompanied quotes were stored in NVivo. At this phase, codes were concise and descriptive in nature and for some used the words of the participants (Braun and Clarke 2013). Initially codes overlapped, however were revisited and refined by the PhD candidate.

Step 3 – Generating themes

Themes were generated by reviewing and combining codes defined in step 2, reviewing original field notes and noticing similarities and overlaps using visual mind maps and matrices (Braun and Clarke 2013). Themes were generated as an overarching description of the pattern of meaning and the central concept, containing lots of different ideas. At this stage, themes and ideas were discussed and presented to colleagues and supervisors with expertise in qualitative research.

Step 4 – Reviewing themes

Once themes were generated, they were reviewed to ensure that they reflected what was in the raw text (Braun and Clarke 2013). Where appropriate, collected extracts from the data were moved to fit with different or more relevant themes. At this stage, an additional search of the raw data ensured that no codes had been missed.

Step 5 – Defining and naming themes

The penultimate step involved the PhD candidate in creating a detailed analysis of each theme and creating a name to encapsulate the essence of the theme. This was conducted alongside discussions with the experienced supervisory team, which allowed opportunity for reflection on codes, themes and assumptions being made from the dataset. Where possible, direct quotes from participants were used to define the themes and ensure the essence of the text was not lost.

Step 6 – Producing the report

Research findings from qualitative interviews are presented in 0. This section is developed by intertwining data extracts with the analytic account and linking with other literature (Braun et al. 2019b).

4.11 Quality assurance for the study conduct, data collection and analysis

Broadly speaking from a pragmatic viewpoint (described further in section 3.2.1, page 72), reliability and validity can be interpreted and recognised by assessing the credibility of both quantitative and qualitative research methods (Noble and Smith 2015). Qualitative research must demonstrate rigour, associated with openness, relevance to practice and congruence of the methodological approach. Quality criteria to assess quantitative data collection and analysis are defined as 'reliability' (whether the results can be replicated if the study was repeated using similar methods) and 'validity' (accuracy of the results) (Noble and Smith 2015).

In this study, a pre-test and post-test design was used to establish feasibility, following a strict study protocol. Selecting quality instruments for data collection supported high reliability and construct validity of quantitative data (Creswell and Plano Clark 2018). Demographic data collected from medical notes used instruments appropriate for use in the hospital setting for people after stroke. For example, Stratton et al. (2004); Sharma et al. (2017) showed that a MUST score for estimating the risk of malnutrition can be confidently delivered in acute settings with regard to validity. In addition, an NIHS score provides the most prognostic information with high overall accuracy and sensitivity for baseline severity of neurological impairment (Muir et al. 1996). Using digital photos to measure dietary intake in hospital is shown to have good inter and intra-rater reliability and allows images to be re-examined and re-estimated if an error is indicated (Navarro et al. 2014). Further assessment of inter-rater reliability is assessed in this study for use with finger food.

Quality of qualitative data is assessed using the constructs of 'trustworthiness'. The assessment of rigour within qualitative research has been widely debated, due to the subjective interpretations of data, leading to the potential for researcher bias (Seale and Silverman 1997). To ensure quality measures and rigour within qualitative research, systematic and clear data collection and analysis procedures are encouraged (O'Reilly and Kiyimba 2015). A key feature of qualitative data collection, analysis, and reporting is for the researcher to remain as neutral as possible, taking caution not to influence the research (Snape and Spencer 2012). However, it is important to acknowledge that true neutrality and objectivity can never be attained, nor should it be desired. The researcher's personal interpretations and perspectives should be acknowledged as important perspectives of reality (Snape and Spencer 2012).

4.11.1 Trustworthiness within qualitative processes

Trustworthiness in qualitative research represents the level of confidence in data, interpretation and methods employed to confirm study quality (Polit and Beck 2013). For this study, Guba's constructs of 'trustworthiness' are used (Lincoln and Guba 1985), which are presented in Table 4-9. These constructs are highly cited within qualitative research, focusing on credibility, transferability, dependability and confirmability.

Table 4-9 Description of constructs of trustworthiness (Lincoln and Guba 1985)

Guba's construct of Trustworthiness	**Description of construct**
Credibility	Assurance that the findings represent the 'truth'.
Transferability	The applicability of findings in other contexts.
Dependability	Consistency of findings and findings that could be repeated.
Confirmability	The extent to which findings show a level of neutrality and/or are shaped by the researcher.

4.11.1.1 Strategies to establish credibility

Credibility aims to assure that findings represent the truth (Lincoln and Guba 1985). There are no methods which can assure credible conclusions; however, strategies can evaluate and increase authentication of results. Where researchers are the instrument for data collection and analysis, this is inevitably conducted with their lens and views imposing on the data. Strategies used for this study include, prolonged engagement, peer debriefing and triangulation (Lincoln and Guba 1985). Observations within this programme of research took place over nine months of data collection, meaning there was long lasting engagement from the researcher to gain rich data (Korstjens and Moser 2018). Conceptualising themes with experienced supervisors was used to support development of themes and skills in thematic analysis. Supervisors were provided with transcripts to read and support verification of themes. A full audit trail of decisions made ensured transparent and thorough analysis procedures (O'Reilly and Kiyimba 2015). The audit trail is presented in Appendix S.

4.11.1.2 Strategies to establish transferability

Transferability is difficult to account for in qualitative research, due to the subjectivity and individualised naturalistic enquiry (Murphy and Yielder 2010). To support transferability to different clinical settings, rich descriptions of contexts and settings are provided throughout the chapter to allow readers to fully understand how the research will relate to other contexts (Korstjens and Moser 2018).

4.11.1.3 Strategies to establish dependability

To ensure consistency of findings, dependability is achieved through a full audit trail from methodology to write up (Murphy and Yielder 2010). To achieve this, reflective notes stored as ‘memos’ in NVivo 12 (QSR International 2020) were used. A clear trail from coding to theme generation is provided in Appendix S.

4.11.1.4 Strategies to establish confirmability

Reflexivity provides confirmability in the research. Reflexivity is an iterative process in which the researcher identifies their own effects on the research and the impact of their own views and beliefs (O'Reilly and Kiyimba 2015). It involves reflecting and questioning the actions of the researcher at all points of inquiry (Durdella 2017).

For this study, a reflective journal was kept supporting reflexivity and for the PhD candidate to self-reflect on her impact to the research (Finlay and Gough 2008). Writing reflexively allowed human subjectivity to be acknowledged (Braun et al. 2019a), as objectivity in qualitative research is neither possible nor desired (Ahern 1999). The potential for biases to influence observation and analysis was minimised using reflexivity prior to the study beginning, by defining personal values, during and post observations to recognise feelings indicating lack of neutrality, and during analysis through regular supervision between the PhD candidate and supervisors during which preconceptions were identified, challenged and bracketed from the study (Ahern 1999). Within the journal, the social GGRRAACCEESS model was used to help the PhD candidate to reflect on the impact on the context of the interviews taking place (Burnham, 1992, 1993; Roper-Hall, 1998). This model enables the researcher to think rigorously about the way she interacts within the data, considering gender, geography, race, religion, age, ability, appearance, class, culture, ethnicity, education, employment, sexuality, sexual orientation, spirituality.

As the PhD candidate is a SLT and has previously worked in the clinical area, some may assume that preconceived ideas when entering the environment are impossible to avoid or views may be altered by the viewpoint. The PhD candidate's background was made explicit throughout the data collection process and was beneficial in identifying gatekeepers for the study.

4.12 Patient and public involvement (PPI)

Patient and public members were used to review participant, consultee and staff information sheets to ensure they were easily read and understood by members of the public. To obtain feedback, the information sheets were sent via email to an NHS Trust PPI database. The database contained 163 email addresses of adults aged 16 years above who have consented to receive emails to comment on research ideas and proposals. The database was managed by the Patient and Public Involvement Officers at the NHS Trust site. Five anonymised participants sent comments back to the PhD candidate for consideration. Examples of comments received from this PPI feedback are shown in Figure 4-7. Participant information sheets were reviewed based upon comments received.

"I have read both leaflets and they are, in the majority, clear and informative. My only comment is that more emphasis should be placed on the fact that the finger food contains all the correct nutrients needed by recovering patients."

"I have reviewed the documents and do not have any comments to make on them. I think they are clearly written and explain the purpose and methodology of the research very well."

"I have looked through the document and found that it flows well and is easy to understand. There were two spelling errors which I have corrected."

"I wonder whether after they have conducted this trial on 'looking at the acceptability and feasibility of finger foods on a hospital stroke ward' whether it could be trialled across the hospital. As I wonder how many patients, after surgery or other hospital visit, are hungry and need to eat something. But when confronted with a full plate of dinner, actually can't eat it all, so end up wasting food. Wonder whether being given the option of finger food may have been better for them. Could cut down on food waste perhaps for this reason?"

Figure 4-7 Comments received from engagement with patient and public involvement group

Views from three PPI representatives supported the design and development of the interview study protocol. Representative were trained mealtime assistant volunteers at the hospital who assisted with preparation and feeding of lunchtime meals at the study site. Views were obtained through 1:1 consultation. All representatives urged the importance of gaining patient's views and experiences during the trial of finger food. Representatives alluded to potential difficulties interviewing family members over lunchtime as they were not often present. They felt that it would be important to consider the views of staff on the ward through interviews and to include student nurses, where possible, who were often involved in mealtime processes and procedures. The study protocol was therefore designed to interview patients on the ward, inviting relatives to join the interview at the patient's digression and recruiting a diverse range of staff.

4.13 Research governance and ethics

The study protocol was peer reviewed internally at the University of Southampton and received approval from University of Southampton Research and Governance office (ERGO) on 06/12/18. The protocol and associated documents were submitted via the Integrated Research Application System (IRAS), a system for applying for the permissions and approvals for health and social care research in the UK. Approval from the Health Research Authority and Research ethics committee (IRAS number: 240341) was gained on 29/11/18 as per Appendix T. Permission to undertake the study by the hospital research and development team was gained on 11/12/18. The study was registered on clinicaltrials.gov (NCT03835455).

Important ethical decisions were considered during the study design to ensure the principles for good research practice described by Economic and Social Research Council (2019) were abided by:

- Maximise benefit and minimise harm
- Respect rights and dignity
- Voluntary and fully informed consent
- Integrity and transparency
- Responsible and accountable
- Explicit conflicts of interest.

As the PhD candidate is a registered SLT, the Health Care and Professions Council (HCPC) standards were adhered to (Health and Care Professionals Council 2016). The only ethical area raised through the ethical review process was interviewing participants who were acutely unwell patient.

4.13.1 Confidentiality and anonymity

Management of information about the hospital wards, and personal data on consent forms, was in line with the General Data Protection Regulation (GDPR) published in 2018 (Information Commissioners Office (ICO) 2018). All patient-identifiable information obtained from the study participants was treated as confidential. The process of confidentiality was ascertained throughout and discussed with participants prior to data collection. A patient-identifiable research number generated on consent represented each participant throughout the study. Data collected on the paper form were transferred into a digital format at the quickest available time point, saved on a password-protected computer database and paper files shredded. All names were anonymised using pseudonyms throughout the study and the write up.

Data were stored securely and destroyed in accordance with the University of Southampton data management policy (University of Southampton 2019). All audio files were uploaded to a password-protected computer and files deleted as soon as possible. Any paper documents relating to the study were filed in a locked cabinet at the University of Southampton. Patient recruitment information was uploaded to an NHS password protected site (EDGE, version 2.0.56) to support collection of feasibility data and to be in line with expectations from the NHS Trust.

4.13.2 Responsibility and accountability

The PhD candidate acted in accordance with the HCPC standards of conduct, performance and ethics which states: 'You must report any concerns about the safety or well-being of service users promptly and appropriately' (Health and Care Professionals Council 2016). Precautions were discussed and considered prior to commencement of data collection. Any observed malpractice by staff, which put the participant at risk of harm, would be questioned at the time and reported according to local procedures.

Due to the PhD candidate observing at mealtimes on a hospital ward, there were potential risks of harm that could have been observed. For example, patients choking or becoming seriously unwell. The PhD candidate held a contract with the NHS Trust and had permission to undertake the observational research from her manager. The PhD candidate met all statutory and mandatory training requirements as a staff member of the NHS hospital Trust. If a participant required immediate medical intervention, the protocol and IRAS ethics form stated that the PhD candidate would immediately inform the registered nurse in charge to escalate the situation. As a registered SLT, the PhD candidate had a professional duty to intervene and call for help. HCPC standards state that: 'You must keep within your scope of practice by only practising in the areas you have appropriate knowledge, skills and experience for' (Health and Care Professionals Council 2016).

The protocol stated clear guidelines on how the researcher should conduct the observations. If any participants showed signs of ill-being, directly resulting from the presence of the researcher, the observations were stopped. This was interpreted as a participant withdrawing consent for the study. Indicators of ill-being included: anxiety, fear, physical discomfort, agitation, bodily tension, despair, anger or swallowing difficulties. Data collected up until this point would remain in the study and participants were informed of this in the Patient Information Sheet (Appendix I).

Participants were assured of their confidentiality during observations, unless there was observation of a person being put at risk through malpractice. In this case a requirement to breach confidentiality could be perceived as essential within the reporting process. This was deemed in line with the Speech and Language Therapy standards of proficiency set out by the Health and Care Professionals council (Health and Care Professionals Council 2016)

4.14 Chapter conclusion

Chapter four has used headings from the CONSORT pilot and feasibility extension guidelines to fully describe methods for a prospective, before and after intervention, feasibility study. The chapter included both quantitative and qualitative methods for data collection and analysis. Pre-specified criteria were defined and will be revisited during the mixed methods analysis to allow interpretations to be made regarding whether to proceed with a future trial.

Being a feasibility study, the design of this study will not necessarily imitate the design of a larger study but will provide results to answer the key uncertainties for a future study. Chapter four has highlighted key quality assurance, research governance and ethical considerations for conducting the study on a hospital ward which should also be considered in a future, larger trial.

The two following chapters present the results from this feasibility study. Chapter five presents feasibility findings including recruitment, retention, quantitative outcome data and results from the mealtime observations. Chapter Six presents findings regarding acceptability of the intervention from qualitative interviews with participants who were patients and members of staff.

Chapter 5 **Feasibility findings (study processes, outcomes, and intervention delivery)**

5.1 Introduction

To ensure rigour and effective reporting, findings from this feasibility study relating to study processes and outcomes are presented in line with the key headings from the CONSORT guidelines (extension for pilot and feasibility trials) (Eldridge et al. 2016a). These guidelines are recommended in the MRC complex interventions guidance to ensure that key information is available for replication studies (Craig et al. 2008). A summary checklist of the CONSORT guidelines is shown in Appendix F.

The aim of this feasibility study was to assess whether a future study to evaluate effectiveness of a finger food menu intervention could be delivered. This chapter will assess whether the methodological approaches selected in this study are robust and achievable, including recruitment and data collection processes. This chapter incorporates qualitative findings from the mealtime observations which give key indications to how the intervention was used in the ward environment. It is important to note that the aim of the feasibility study was not to assess the effectiveness of this intervention (Lancaster 2015); it was instead to indicate the impact of finger foods on the population of interest.

The findings from qualitative interviews addressing the acceptability of the finger food menu intervention are presented separately in Chapter 6 to ensure that findings are defined in full (O'Cathain et al. 2015).

5.2 Participant flow

The participant flow diagram recommended by Eldridge et al. (2016a) in the CONSORT guidelines has been modified for this study and presented in Figure 5-1. It displays data regarding participant flow through the study for the ‘before and after’ quantitative data collection and mealtime observations, including reasons for exclusion.

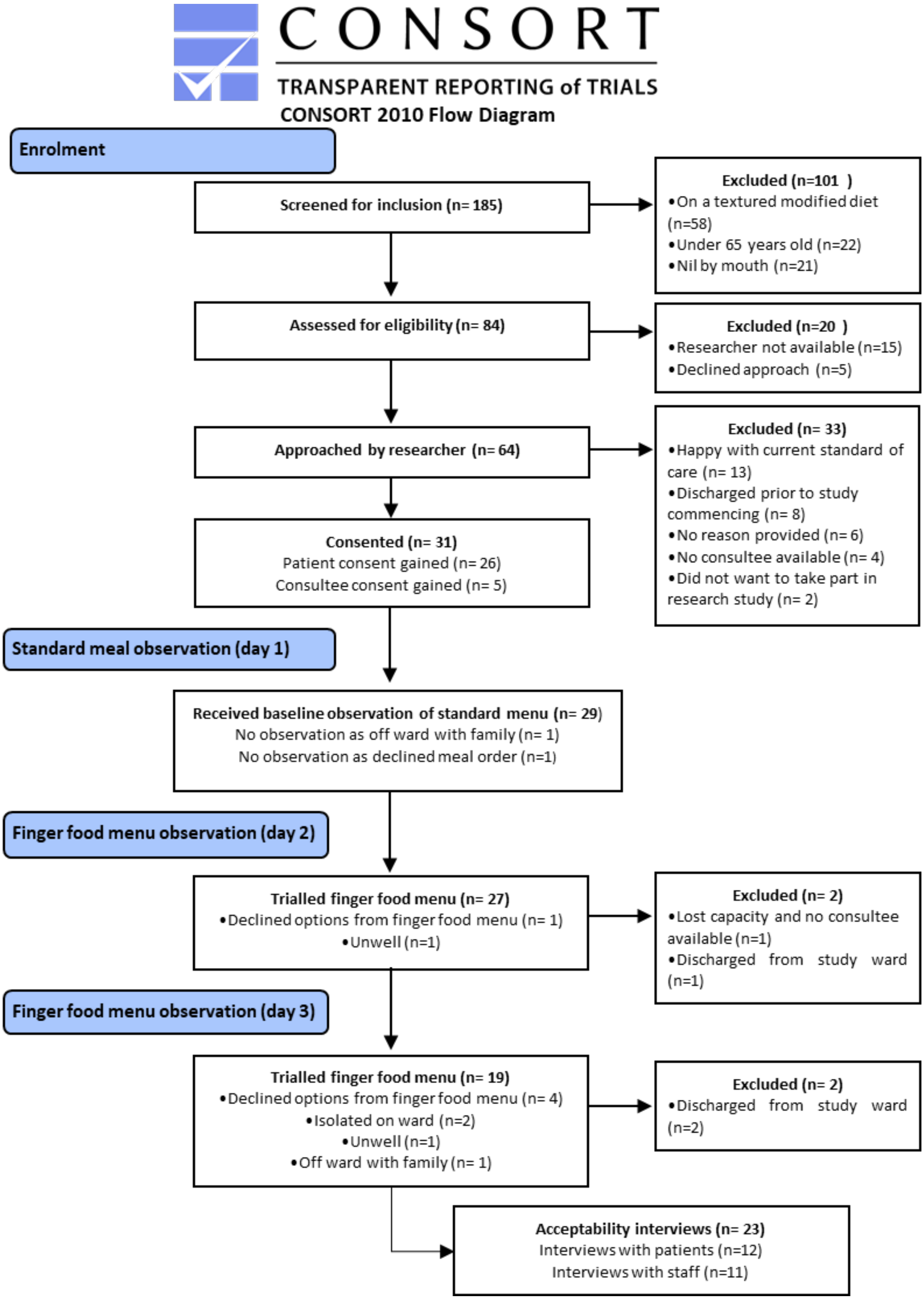


Figure 5-1 Participant flow diagram

5.3 Recruitment

Recruitment occurred between January 2019 and August 2019. The number of participants recruited per month are shown in Figure 5-2. Six participants were recruited in February 2019, which was the highest number of participants recruited in a singular month. During April 2019, the ward closed due to an outbreak of norovirus and diarrhoea and vomiting. This halted recruitment for a short period, indicated by the fall in recruitment rate. A similar decline in recruitment was seen in June 2019, when the PhD candidate took a holiday.

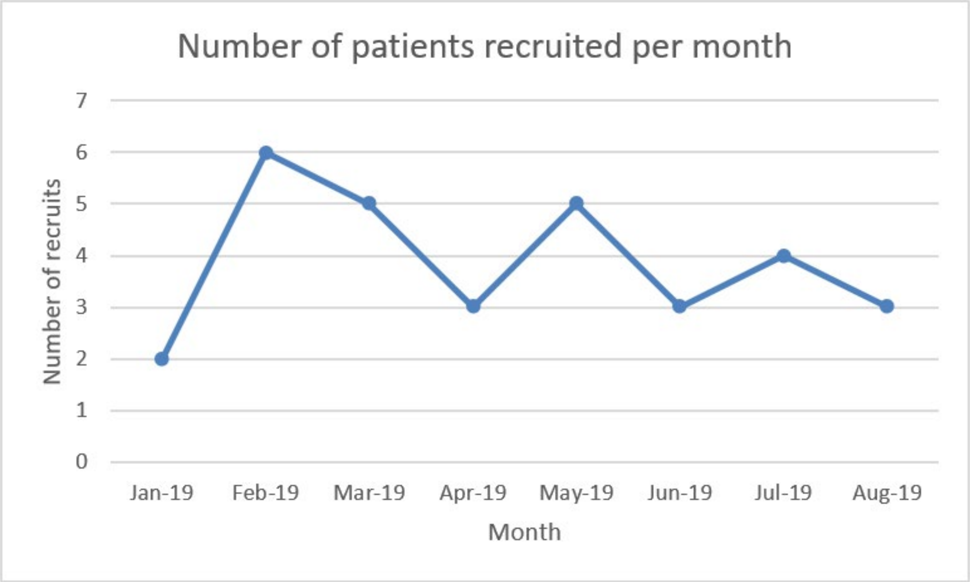


Figure 5-2 Number of patients recruited to study per month

Figure 5-3 shows overall recruitment to the study was as expected. The recruitment target for this study was set during the planning stage, pragmatically based on how many participants the solo researcher could recruit per month within an eight-month data collection period. The target recruitment sample was 30-32 participants. Recruitment was halted at 31 participants when the maximum recruitment time frame was reached.

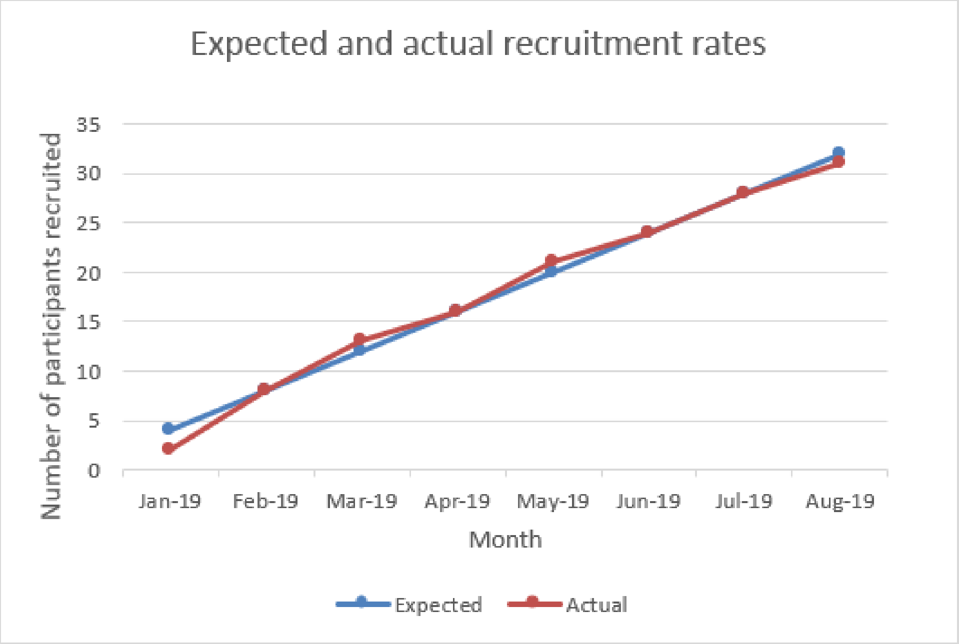


Figure 5-3 Expected and actual recruitment rates

5.3.1 Support with recruitment

Key members of the clinical team supported recruitment by identifying patients who met the eligibility criteria. This included nursing staff and therapy staff (particularly physiotherapy assistants and occupational therapy assistants) and the catering ward host. Stroke rehabilitation guidelines from National Institute of Clinical Excellence NICE (2016) recommend 45 minutes of daily therapy input for patients after stroke, which meant therapy staff were highly involved in patient care. The ward host (providing catering services) also acted as a useful source of information regarding patients able to manage Level 7 regular diets, a key component to eligibility criteria.

5.3.2 Meeting eligibility criteria

Eligibility criteria were set to define the study sample. Figure 5-1 displays reasons for exclusion of potential participants based on eligibility criteria. Sixty five percent of patients were excluded at screening due to either being on a textured modified diet, nil by mouth, or aged under 65.

The single PhD candidate was not able to approach 15 patients for inclusion, due to time constraints. One patient was ineligible, due to not being able to understand English. Despite this not being part of the eligibility criteria, there was no opportunity outlined in the protocol to support use of an interpreter to approach and inform the patient of the study.

Following approach by the researcher, eight patients were discharged from the study ward and therefore ineligible for the study.

5.3.3 Patients declining to participate

As shown in Figure 5-1, fifty two percent of patients approached by the PhD candidate declined to participate in the study (33 of 64). Thirteen patients reported being satisfied with the current food options and declined to participate further (n=13, 40%). These patients had received information sheets (Appendix I and Appendix J) which stated that the study would involve trialling a new finger food menu and provided some examples of food; however, it did not provide a copy of the new menu.

Two patients specifically declined to take part as they were not interested in being involved in research.

5.3.4 Consent process

Five (16%) participants of 31 who joined the study were unable to provide valid informed consent, and personal consultee consent was gained (Department of Health Scientific Development and Bioethics Division 2008). There was a requirement for written consent from personal consultees who were typically visiting relatives on the ward. There were four cases where a suitable personal consultee could not be contacted or was not able to visit the ward, so these patients could not be recruited.

Consultee consent was required for participants who lost capacity during the data collection period, to allow continuation in the study. During the acute stages for people after stroke, changes in cognitive function and fluctuating capacity is common. During this feasibility study, one participant was withdrawn by the PhD candidate prior to data collection for day 2 due to a loss of capacity and a personal consultee not being available.

5.3.5 Rates of attrition

There were high rates of attrition across the three lunchtime observations. Figure 5-4 displays the retention of participants during the three lunchtime observation periods. Full outcome measures could be completed for 19 participants, shown by the bar represented by finger food menu observation 3.

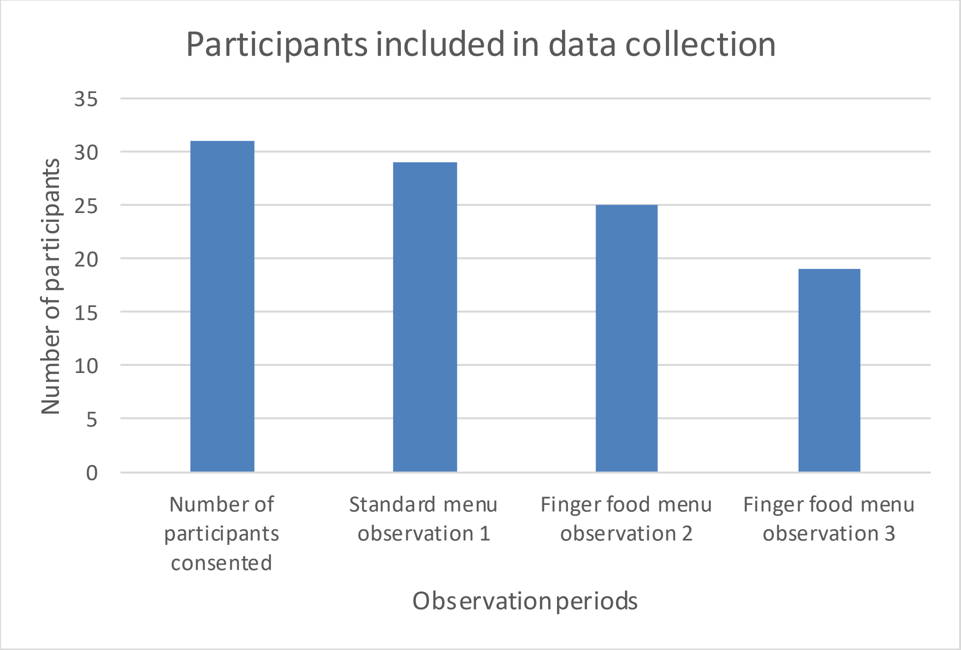


Figure 5-4 Number of participants enrolled in data collection periods

Reasons that data could not be collected for participants over three lunchtime observations are displayed in Figure 5-1. These were considered as factors relating to the acute environment, such as patient discharges and being unwell, alongside participants declining options from the finger food menu. One participant declined to trial finger foods over day two and day three of the study. Four participants chose not to order from the finger food menu on day three of data collection.

During the standard menu observation and third day of data collection, one participant was off the ward with family. This participant consented to participate in a follow up interview to fully explore the reason for this.

5.4 Baseline data

Baseline demographic and clinical characteristics for each group included in data collection days are presented in Table 5-1. Due to the loss of participants throughout the data collection period, it was important to understand the sample of population that took part consistently over the three days and to acknowledge any trends or differences in those who dropped out of the study, prior to study completion.

Table 5-1 Participant characteristics presented by day

Characteristic		**CONSENT**	**%**	**DAY 1**	**%**	**DAY 2**	**%**	**DAY 3**	**%**
Participants		31		29		27		19	
Mean length of stay (days)		17.42		16.97		16.63		15.68	
Gender	Male	15	48%	13	45%	13	48%	9	47%
	Female	16	52%	16	55%	14	52%	10	53%
Age (years)	65-80	14	45%	12	41%	13	48%	10	53%
	80+	17	55%	17	59%	14	52%	9	47%
BMI on admission [1] [2]	<18.5(Underweight)	1	3%	1	4%	1	4%	1	6%
	18.5-24.9(Healthy)	13	45%	13	48%	9	36%	5	29%
	25-29.9(Overweight)	7	24%	6	22%	7	28%	7	41%
	30-39.9(Obese)	8	28%	7	26%	8	32%	4	24%
MUST score on admission [1]	Low risk	22	76%	21	78%	20	80%	13	76%
	Medium risk	1	3%	0	0%	1	4%	0	0%
	High risk	6	21%	6	22%	4	16%	4	24%
Input from dietitian during admission	Yes	11	35%	10	35%	10	37%	7	37%
	No	20	65%	19	65%	17	63%	12	63%
NIHSS [3]	0 (No stroke)	2	6%	2	7%	1	4%	0	0%
	1-4 (Minor)	12	39%	11	38%	11	41%	9	47%
	5-15 (Moderate)	13	42%	12	41%	11	41%	7	37%
	16-20 (Mod. to severe)	4	13%	4	14%	4	14%	3	16%
	21-42 (Severe)	0	0%	0	0%	0	0%	0	0%
NIHSS Motor arm on admission (right and left) [3] [4]	No drift	9	30%	9	32%	7	27%	5	28%
	Drift	10	33%	10	36%	9	34%	7	39%
	Some effort	5	17%	3	11%	5	19%	3	16%
	No effort	4	13%	4	14%	3	12%	1	6%
	No movement	2	7%	2	7%	2	8%	2	11%
Evidence of impairment of cognition	Yes	29	94%	27	93%	25	93%	19	100%
	No	2	6%	2	7%	2	7%	0	0%

[1] Two missing values

[2] BMI ranges as per NHS https://www.nhs.uk/common-health-questions/lifestyle/what-is-the-body-mass-index-bmi/

[3] National Institute of Health Stroke Scale

[4] One missing value

5.4.1 Comparison between participant characteristics across data collection points

Due to the small sample size in this study, it is difficult to fully compare characteristics between groups. Overall, Table 5-1 shows the gender ratio of males and females was stable throughout each day of data collection. Ages of participants remained equitable, with an equal balance between those aged 65-80 and above 80 years old.

Participants with a BMI in the 'healthy' range appeared to drop out earlier within the study as opposed to those with a BMI in the 'overweight' range. Two participants who had 'no movement' of one upper limb participated in all three days of data collection. Ninety four percent of participants had evidence of cognitive impairment on consent to the study. On day three of data collection, 100% of participants had evidence of cognitive impairment.

Table 5-1 shows evidence of missing values, where baseline characteristic data could not be collected from medical records. Despite recommendations for all patients to be screened for risk of malnutrition on admission to hospital (NICE 2012b), BMI and MUST scores on admission could not be collected for two participants. NIHSS (Goldstein and Samsa 1997) was reported for all participants however, for one participant who had been transferred from a different hospital, the breakdown of NIHSS score was not available.

5.5 Numbers analysed

Full outcome measures relating to dietary intake were collected for 19 participants. Figure 5-1 illustrates where full outcome measures could not be reported for all participants. To avoid bias in results, cases of missing data were removed.

5.6 Outcomes

Key outcomes for this study related to:

- The ability to collect valid and trustworthy quantitative and qualitative data
- The reliability of chosen outcome measures
- Initial indications regarding the impact of finger foods on dietary intake
- Economic outcomes
- The intervention delivery based upon thematic analysis of field note data obtained from mealtime observations.

5.6.1 Outcomes relating to data collection processes

5.6.1.1 Feasibility of taking digital photos to collect dietary intake data

Overall, 149 digital photographs of plates were taken and stored for data analysis away from the study ward. Photographs of trays were taken prior to being given to the participant by the ward host, away from the participant's view, and then taken prior to the ward host collection. A rapport built between the PhD candidate and ward catering host supported this. During this small study, with a single researcher it was easy for the PhD candidate to identify the plates from photos and save accurately based on date and time taken. However, in a larger study it would be important to label plates prior to digital image taking to ensure no mix up in reporting.

There was one occasion where the digital image did not capture due to a software error. In this instant, plate waste estimates were based upon visual estimation of the plate.

5.6.1.2 Feasibility of conducting mealtime observations

Overall, 83 lunchtime meals were observed across standard and finger food mealtimes, which provided a range of field note data. This section addresses the feasibility of conducting mealtime observations and the feasibility of having observations conducted by the PhD candidate who was previously a member of staff. Timings and durations of the observations and challenges to conducting observations on the ward based on the PhD candidate's reflections are detailed below.

The mean duration for each lunchtime observation (from tray delivery to just prior to tray collection) was 40 minutes, ranging from 18 minutes to 1 hour 42 minutes per observation. Timings for observations varied depending on when the meals were served, whether the participant was on the ward at that time and length of time taken to eat. Typically, lunchtime meals were served on the ward at 12:30pm. A maximum of two participants were observed at any one time on each bay by the single PhD candidate to ensure detailed field notes could be made.

On occasions where there were lots of visitors in the bay over lunchtime meals, placement of the PhD candidate to observe the participant over mealtime was a challenge due to the limited space on the ward. Where there were many visitors in the bay, there was also increased noise level which made it difficult for the PhD candidate to hear all verbal interactions between staff or visitors and participants. On these occasions, the researcher positioned herself outside the bay, making sure that there was space to view. This is shown in the following exert from observational field notes.

> *Sitting outside of the bay slightly during this observation as it is busy in the bay and visitors are present with 045. No space for another chair in the bay without being in the way of the nurses. Feels slightly awkward conducting observations when participant has visitors present. Comment made by visitors initially regarding participation in the study and being observed, however visitors appeared to become less aware of the researcher observing as time goes on (Reflective Memo_045)*

During the data collection period, the PhD candidate had a unique perspective, orientated as both an insider and outsider (as documented in section 3.2). At the time of data collection, she was not working clinically on the ward; however, she had prior knowledge of ward systems and relationships with some of the staff members still working on the ward. These staff members were aware of the researcher's clinical role as an SLT. This perspective posed some challenges to conducting mealtime observations on the ward as documented in reflective memos.

Initially, during mealtime observations staff behaviours appeared to be influenced by the PhD candidate's presence, with staff members speaking aloud and reflecting on clinical practice, as shown by the field note below.

> *"014 do you want me to help you? We're being watched so don't choke." HCA feeds 014 remainder of ice cream. (Field note, Participant 007, Finger food meal)*

The PhD candidate's insider role may have impacted on clinical staff's behaviour, knowing that a professional SLT known to focus on swallowing safety was observing the mealtime. Asselin (2003) describes a higher risk of role confusion where research is conducted in a familiar setting, with difficulties in separating activities from clinician to researcher. To define her role, the researcher introduced herself, showed her university badge and clarified her role during each research visit, and made it clear that none of the patients on the ward were under her clinical care at the time. As the study progressed, staff began to associate the researcher with data collection for the study as opposed to her clinical role. Making this distinction between clinical and research role set clear boundaries to ensure staff did not rely on the researcher for clinical tasks. Similarly, where participants or other patients on the bay asked for support, the PhD candidate did not provide clinical support but highlighted her role as a researcher and directed patients towards a member of staff on the ward. At times, staff who were unaware of the researcher's role asked clinical questions relating to patients on the ward. To address this, the researcher provided a reminder to staff of her role and requested staff to address questions to other practitioners working on the ward. As members of staff got more used to the researcher on the ward, interruptions and interactions decreased.

5.6.1.3 Feasibility of conducting interviews

All patient participants approached for interviews agreed to participate. In agreement with the participant, all interviews were held at the bedside, despite the offer of a private space for recording. Curtains were drawn to avoid interruptions. Where interviews were interrupted by staff or participants requiring nursing support, interviews were paused and reconvened later the same day. Noise levels on the ward, initially a concern for the PhD candidate, did not affect the recording quality and all recordings were audible for accurate transcription. Interviews with patient participants on the study ward were short in duration (mean length 16 minutes), often terminated due to participants requiring repositioning from nursing staff or support with personal care.

Staff interviews took place off the ward in a research room. Initially, it proved difficult to organise staff interview times. Interviews were organised to be outside of staff core shift hours. However, members of staff were often requested to work overtime or change shift patterns at late notice to cover for staff shortages, which meant that some interviews were not attended. The PhD candidate had a discussion with the ward manager who later supported some participants to change shift patterns to accommodate scheduled interviews. Photographs presented to staff in interviews supported staff to reflect on the provision of the finger food menu options and supported recall.

Overall, this mixed methods study used data collection methods that could be conducted efficiently and effectively in the hospital ward environment. Key considerations to ensuring these methods can be replicated in a future study will be further discussed in Chapter 7.

5.6.2 Outcome measure performance

One of the objectives for this feasibility study was to understand whether selected dietary intake outcomes were appropriate, reliable, and valid for use in a future study. Dietary intake from baseline and intervention periods were assessed based upon plate waste estimations and used to calculate nutrient information.

5.6.2.1 Plate waste estimations

Plate waste was estimated for individual food items provided by the hospital. In total estimations from 275 items were reported, including both main meal and dessert items.

Figure 5-5 and Figure 5-6 show clearly that overall plate waste estimations between standard menu items and finger food menu items were similar. The majority of food items were eaten with no plate waste remaining across standard and finger food meal items. This meant that in most cases, participants ate all the food item provided. There was only a small proportion of cases across the standard and finger food meal items where no food items were eaten and 100% of food remained on the tray.

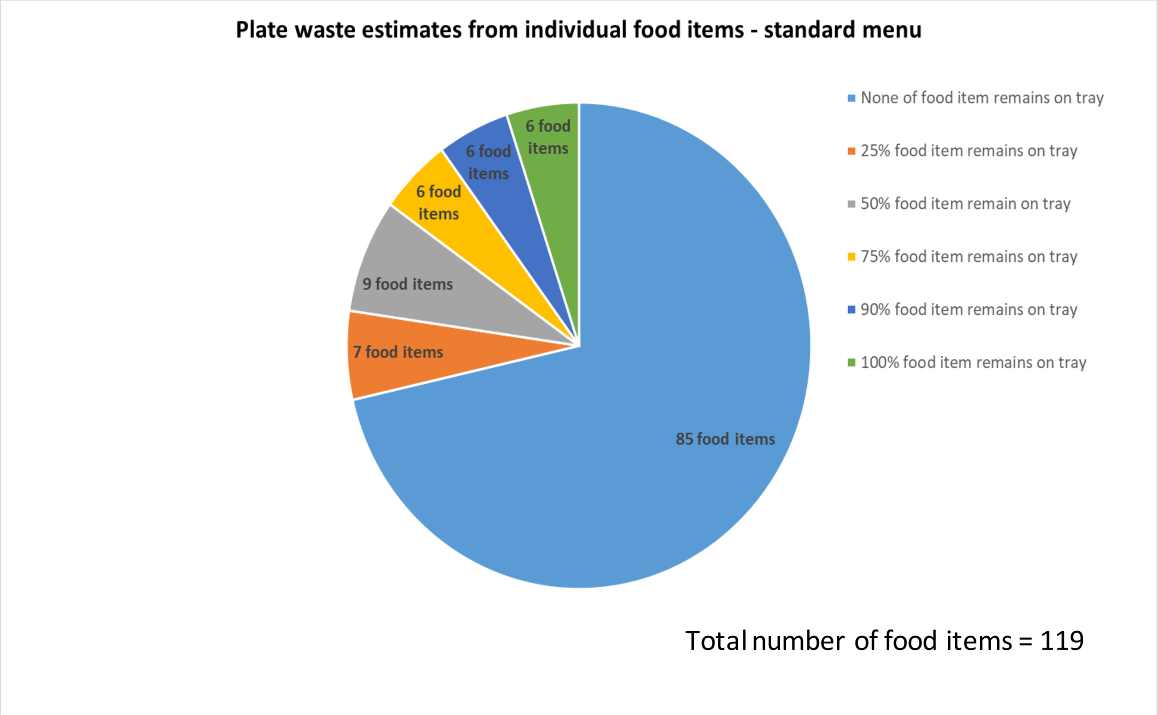


Figure 5-5 Plate waste from standard menu items

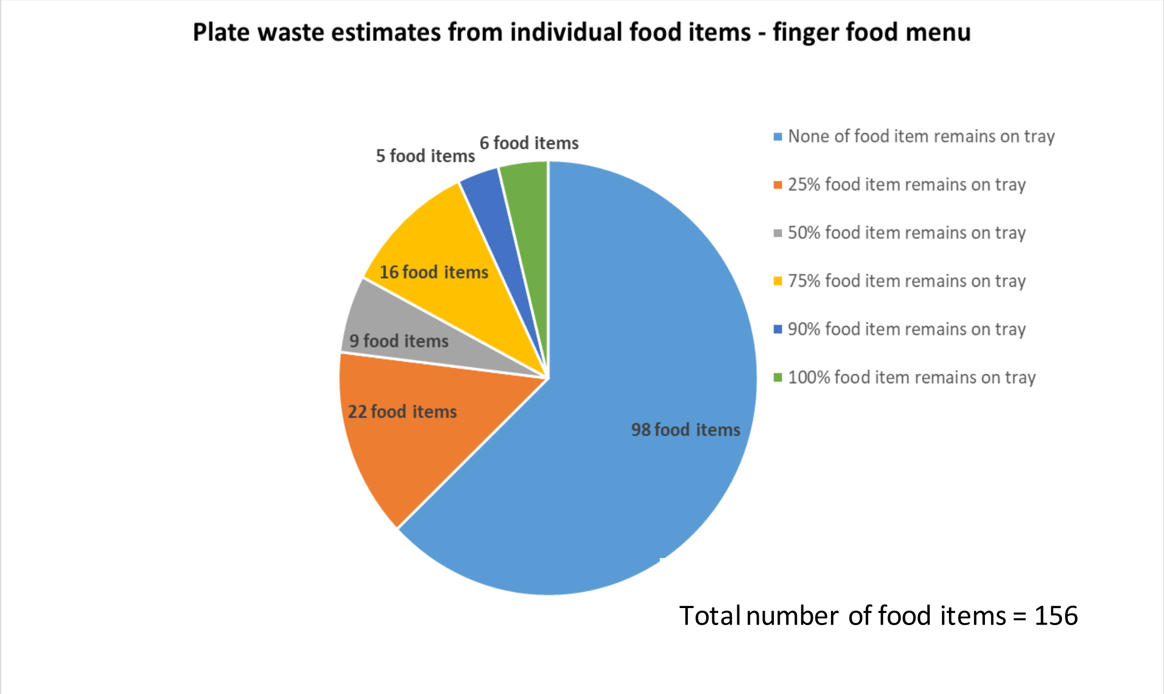


Figure 5-6 Plate waste from finger food menu items

5.6.2.2 Inter-rater reliability

It is anticipated that in a future, larger trial, a team of researchers will be collecting and analysing data relating to dietary intake. Therefore, it is important that the dietary intake measure can be estimated reliably amongst a team of trained researchers.

Table 5-2 displays plate waste scores of meal item plate waste estimated by both researchers. The highlighted cells show agreement between the two independent researchers. Overall, agreement between estimated consumption of food items rated was 84.36% (n=232). Table 5-2 shows a high level of agreement where 'none of the food items remained on tray' (97.8%). Most variability was within the '90% of food item remained on tray' section, which suggest that further training on what this looked like should be provided.

Table 5-2 Crosstabulation of estimated plate waste scores from two independent researchers

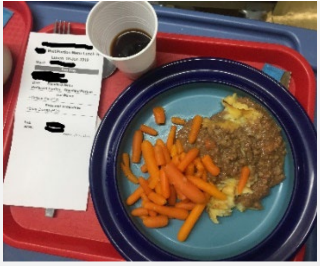
		Researcher 2						Total
		None of food item remains on tray	25% food item remain on tray	50% food item remain on tray	75% food item remain on tray	90% food item remain on tray	100% food item remain on tray	
Researcher 1	None of food item remains on tray	177	6	0	0	0	0	183
	25% food item remain on tray	4	21	4	0	0	0	29
	50% food item remain on tray	0	2	9	4	2	1	18
	75% food item remain on tray	0	1	1	9	8	3	22
	90% food item remain on tray	0	0	0	3	7	1	11
	100% food item remain on tray	0	0	0	0	3	9	12
Total		181	30	14	16	20	14	275

Cohen's Kappa was run to determine level of agreement between the two researcher's judgement of meal item plate waste using 275 items. There was 'good' agreement between the judgements, κ=0.709 (95% CI .64 to .77), p<0.001 based on the guidelines set from (Altman 1990).

5.6.2.3 Nutrient intake from plate waste estimations

Nutrient intake was based on estimations of plate waste recorded from digital photographs (Navarro et al. 2014 Williamson, 2003 #317).

Table 5-3, Table 5-4, and Table 5-5 provide examples of nutrient intake data for individual participants. Digital photographs of plates taken at serving and prior to collection are presented, with corresponding estimates of plate waste per meal item and related energy (in kcal), protein, fat and carbohydrate intake. Each table displays intake for a single participant over the three

	Plate at serving	**Plate prior to collection**	**Meal item (plate waste %)**	**Dietary intake**
Standard meal (day 1)			Cottage pie (50%) Baby carrots (25%)	**Energy:** 124kcal **Protein:** 7.5g **Fat:** 6.5g **Carbs:** 8.5g
Finger food meal (day 2)			Cheese and tomato pizza (50%) Baby carrots (25%) Banana (25%) Peaches (25%)	**Energy:** 350.75kcal **Protein:** 11.20g **Fat:** 9.38g **Carbs:** 55.55g
Finger food meal (day 3)			Sausage roll (75%) Roast potaoes (75%) Madeira cake (0%)	**Energy:** 243kcal **Protein:** 4.63g **Fat:** 12.68g **Carbs:** 27.50g

mealtime observations.

Table 5-3 Example of photo images and dietary intake estimations

Table 5-4 Example of photo images and dietary intake estimations

	Plate at serving	**Plate prior to collection**	**Meal item (plate waste estimate %)**	**Total dietary intake**
Standard meal (Day 1)			Sweet and sour chicken (50%) Rice (25%) Broccoli (90%) Prunes (75%)	**Energy:** 144kcal **Protein:** 6.05g **Fat:** 1.68g **Carbs:** 26.00g

Table 5-4 Example of photo images and dietary intake estimations

	Plate at serving	Plate prior to collection	Meal item (plate waste estimate %)	Total dietary intake
Finger food meal (Day 2)			Sandwich (25%) Chips (75%) Banana (25%) Satsuma (0%)	**Energy:** 430.5kcal **Protein**: 14.40g **Fat**: 15.80g **Carbs:** 58.75g
Finger food meal (Day 3)			Cheese toastie (25%) Banana (25%) Satsuma: (0%)	**Energy:** 370.50kcal **Protein:** 15.50g **Fat:** 13.50g **Carbs:** 46.50g

Table 5-5 Example of photo image dietary intake estimations

	Plate at serving	Plate prior to collection	Meal item (plate waste estimate %)	Total dietary intake
Standard meal (Day 1)	 [redacted]		Soup (0%) Sweet and sour chicken (25%) Rice (25%) Bread roll (0%) Toffee yoghurt (0%)	**Energy:** 728.25kcal **Protein:** 32.18g **Fat:** 14.13g **Carbs:** 116.85g
Finger food meal (Day 2)	 [redacted]		Chicken goujons (0%) Baby carrots (0%) Chips (25%)	**Energy:** 418kcal **Protein:** 18.4g **Fat:** 18.78g **Carbs:** 42.05g

	Plate at serving	**Plate prior to collection**	**Meal item (plate waste estimate %)**	**Total dietary intake**
Finger food meal (Day 3)			Cheese and tomato pizza (25%) Bread roll (50%) Banana (0%) Peaches (0%)	**Energy:** 540.74 kcal **Protein:** 18.25g **Fat:** 14g **Carbs:** 86.75g

Overall, the methods for collecting dietary intake data were appropriate for use on a hospital ward. Photos could be taken simply with a camera on a phone or tablet device and therefore no specific training was required. Plate waste measures using the 6-point scale (Comstock et al. 1981), analysed away from the ward showed good inter-rater agreement between two independent researchers, with limited training. Plate waste estimations could be used alongside data from the catering team to estimate dietary intake.

5.6.3 Indication of effect

An estimate of treatment effect and standard deviation was used to support a calculation of the sample size for a main trial and to show an indication for the effect of the intervention. This section uses descriptive statistics and non-parametric tests as preliminary evidence to support the development of a future study.

5.6.3.1 **Median energy, protein, fat and carbohydrate consumption**

Median dietary intake, range, and interquartile range for each day of data collection is presented in Table 5-6. Dietary intake measures are reported for key nutritional components, including energy (in Kcal), protein, fat and carbohydrates.

Overall, median energy intake was higher during the finger food menu intervention and increased across the two mealtimes using the finger food menu intervention. However, there was a wide range across all three days of data collection.

Median consumption of protein decreased over day two and day three, suggesting the food items provided within the finger food intervention were not as high in protein as those food items consumed within the standard menu.

Median consumption of fat increased over day two and day three of intake and so did carbohydrate consumption. Again, a wide range of results was seen across all days of data collection.

Table 5-6 Median dietary intake for baseline and intervention.

		Standard meal (day 1)	**Finger food meal (day 2)**	**Finger food meal (day 3)**
Total number of meals		19	19	19
Energy consumed (kcal)	Median	419.30	530.00	540.80
	Range (min – max)	911.00 (124.00-1035.00)	780.00 (108.30-888.30)	685.20 (108.00-793.50)
	IQR*	406.0	237.5	415.5
Protein consumed (g)**	Median	20.10	19.50	16.80
	Range (min – max)	27.4 (4.80-32.20)	29.40 (4.30-33.70)	31.10 (4.30-35.40)
	IQR*	17.80	8.80	12.8
Fat consumed (g)**	Median	14.70	18.80	16.40
	Range (min – max)	38.00 (1.70-39.70)	40.70 (2.00-42.70)	41.90 (4.50-46.50)
	IQR*	13.70	19.70	12.10
Carbohydrates consumed (g)**	Median	48.80	68.20	64.00
	Range (min – max)	127.00 (8.50-135.50)	95.80 (12.30-108.10)	101.20 (12.30-101.20)
	IQR*	57.10	26.2	52.80

*** Inter-quartile range**
**** (g) grams consumed**

5.6.3.2 Comparison between standard meal and finger food meal

A Wilcoxon signed rank test was conducted to determine the effect of finger foods on dietary intake compared to the standard foods offered on the hospital stroke rehabilitation ward, using the median difference between two conditions. Considering the small sample size in this feasibility study, normality of data cannot be assumed. Therefore, to determine the statistical significance of these results a Wilcoxon signed rank test was used.

Table 5-7 shows outcomes of Wilcoxon signed-ranked test. Outcomes from 19 participants were included. Based on results from 19 participants, the finger food menu elicited both increases and decreases in nutrient intake (positive difference showing number of participants where scores consumption increased and negative difference showing the number of participants where consumption decreased). There was not a statistically significant increase in the energy, protein, fat or carbohydrate intake when participants ate finger foods as opposed to standard meal. However, there was an indication that overall, there was an increase in the median consumption of energy, fat and carbohydrate intake.

Table 5-7 Results from Wilcoxon signed ranked test

Nutrient	Median difference	Positive difference	Negative difference	Z score	P value
Standard (day 1) VS Finger food (day 2)					
Energy	147 kcal	13	6	1.449	0.147
Protein	2.8g	10	9	1.127	0.260
Fat	3.7g	14	5	1.650	0.099
Carbohydrate	18.9g	13	6	1.650	0.099
Standard (day 1) VS Finger food (day 3)					
Energy	52 kcal	11	8	0.724	0.469
Protein	0.4g	11	8	-0.020	0.984
Fat	1.6g	13	6	0.980	0.327
Carbohydrate	7.6g	12	7	0.805	0.421

Nutrient intake consumption showed a trend towards finger foods providing increased amount of energy, fat and carbohydrate levels when compared with the standard meal. Median differences in intake were higher when comparing day one vs day two, as opposed to day one and day three. The median difference between values were not statistically significant. This was to be expected in the feasibility study and does not specifically suggest that in a future larger trial, significant results would not be seen. This data provides information for a future sample size calculation which is further described in section 5.9.

5.6.4 Economic outcomes

This feasibility study used a cost consequence analysis to report a table of costs and consequences to be considered in a future trial, based upon costs identified within the intervention development stage in section 3.4.8, page 93.

5.6.4.1 Intervention costs

A description of intervention costs is presented in Table 5-8 based on two scenarios.:

Scenario 1 provides details of standard care, where the standard menu is provided and no further intervention.

Scenario 2 provides details of the finger food menu intervention provided in addition to the standard menu.

Table 5-8 Description of costs

	Description of costs
Scenario 1 - Standard menu	• Food costs • Time required for ward hosts to plate up standard menu items.
Scenario 2 - Finger food menu	• Food costs • Time required for ward hosts to prepare finger food meal trays • Production and printing of additional menu • Staff training to support understanding of finger food and who to use it for • Staff costs relevant to time required to support patients over mealtimes.

From the list presented in Table 5-8, food costs were the only item that could be monetised. The additional items listed, but not monetised, are items identified in this feasibility study that organisations should consider resourcing in a future trial. Due to the provision of a new intervention, the number of costs items associated with scenario 2 increased. This is because the provision of a new finger food menu was in addition to the standard menu. Food provision from family was considered, however was supplementary and equal for both scenarios, and therefore not included in the description of costs. Time required for meal preparation was difficult to capture from the feasibility study and was only captured qualitatively within field notes. On occasions the PhD candidate had to support or direct meal preparation so that participants were correctly served with properly prepared finger food. It could therefore be anticipated that on a wider scale, finger foods may require increased time to be presented. This will require further analysis in a future trial.

Cost information provided by the catering were used to describe changes to direct food costs. This was based on what participants who were patients ordered during the trial and costs per meal portion. Estimated costs are presented in Table 5-9.

Table 5-9 Estimated food costs, per meal

	Food costs per meal, (SD), 95%CI
Standard menu	£1.69 (0.66), 95%CI (1.47, 1.92)
Finger food menu	£1.59 (0.65), 95%CI (1.39,1.78)

Food costs estimations showed that the mean costs of offering the finger food menu was cheaper than food costs to provide the standard menu.

5.6.4.2 **Total consequences**

Consequences considered for this study included:

- Food intake
- Plate waste
- Patient satisfaction – engagement with eating, experiences, independence with eating
- Assistance required from staff
- Rates of malnutrition
- Requirement for oral nutrition support or enteral nutrition
- Length of hospital stay
- Complications associated with malnutrition

Median scores between groups were compared for relevant outcome measures and presented in Table 5-10. Additional measures for example patient satisfaction and rates of malnutrition were not assessed quantitively for this study but should be considered for a follow up trial.

Table 5-10 Total consequences for standard and intervention periods

	Plate waste	**Energy intake**	**Protein intake**
Standard menu	Plate waste evident for 29% participants	419.3kcal	20.1g
Finger food menu	Plate waste evident for 37% participants	530kcal	19.5g
Between groups		147 kcal	2.8g

5.6.4.3 Balancing costs and consequences

Due to the limited data collected for this feasibility study a true cost and consequences balance sheet would not be a true representation of the results. However, this exercise has shown important considerations for a future economic evaluation.

Catering providers provided individual food costs, although this cost did not include service costs associated with cooking and presenting. Additional staff costs were difficult to monetise and report on during the small-scale study. The need to evaluate this on a larger scale should be considered in liaison with key stakeholders e.g., the catering providers. Additional staff costs are only likely to need further consideration if catering teams need to employ additional staff. In this study, a similar level of clinical staff was required, despite participants feeling more independent with feeding.

On the consequence side, participants experienced a small, non-significant increase in energy and protein intake with the finger food intervention. This has the potential for decreased rate of malnutrition risk. However, complications and rates of malnutrition are often multifactorial and will tend to have associated consequences, which are difficult to fully attribute to the intervention. This will therefore need to be addressed carefully.

Plate waste has important considerations with regards to sustainability targets and reducing waste and may incur monetary reward for some Trusts. A report by WRAP (2015), a UK-based sustainability charity, highlighted that 0.5 kilograms of food waste are produced per patient per week in hospitals. The report highlighted that typically NHS waste management charging mechanisms are based upon the amount of waste produced, and therefore charges reduce as food waste is reduced (WRAP 2015). The small scale of this study is likely to have a limited impact on food waste and monetary charges, however, if the small difference found in this study is replicated on a larger scale, there is potential for a bigger impact.

5.6.5 Intervention delivery

The aim of conducting the mealtime observations was to understand how the finger food intervention was being used on the study ward with patients after stroke and whether it was used as intended.

Findings from field note observations are presented as themes derived from the data. Themes were supported by overarching domains as detailed in Table 5-11. Themes generated are reported in two distinct sections. The first section aims to describe *how* finger foods were used on the ward, based upon the conceptual model by Keller et al. (2014), described in Figure 1-4 on page 34. Four overarching domains: meal access, meal quality, meal experience and hospital systems originate from the model by Keller et al. (2014), with 'hospital systems' used to encapsulate the higher-level external factors impacting on the intervention and food intake. The theme of 'hospital systems' is also described by Gallant (2019) who used hospital systems in the mixed methods study of mealtimes in hospitals for people with dementia.

Secondly, themes relating to the overarching domain of 'development of the intervention' are described which relate to future recommendations to develop the intervention.

Field notes from standard mealtimes and mealtimes using the finger food intervention were analysed separately. The sections below are composed using comparisons between standard and intervention observation periods. This enabled greater understanding of standard practice and supported awareness of events and actions that occurred during the intervention.

Table 5-11 Key themes generated from mealtime observations

Overarching domain	Themes
Meal Access	Effortful access to meals
	Variations to finger food access
	Enabling independent meal access
	Assistance to support finger food access
Meal Quality	Noticing finger food as different
Meal Experience	The embarrassment of lacking control
Hospital System	Using finger foods in a time bound mealtime task
	Flexibility of finger food in un-prioritised mealtime
	Staff influencing beliefs about using hands to eat
Development of intervention	Time for food preparation
	Special requests and familiarity of food

The text below provides key quotes from fieldnotes which represent each theme. A summary of participant characteristics and related study ID numbers are displayed in Appendix U.

5.6.5.1 Meal access

Meal access is described by Keller et al. (2014) as physical ability to chew and swallow, taste and smell and encompasses the requirement for mealtime support. The fieldnotes created a much richer description regarding the complexities associated with mealtime access of standard food and finger foods, encapsulating the increased efforts involved for people after stroke to access meals, variations in how finger food meals were accessed and assistance required from staff and relatives to support access to finger foods, despite the preference for most participants to be independent with eating.

5.6.5.1.1 Effortful access to meals

As a result of the stroke, participants experienced challenges with motor, perceptual and cognitive access to food, which meant that they needed an increased effort to access all meals. This was often exhibited in the field notes as becoming disengaged or frustrated with the eating task. A frequently observed behaviour was participants putting their head in their hands when mealtimes became a struggle. This behaviour was typically observed where participants had no support or assistance available or used inappropriate cutlery.

> *Makes face – struggling. Slowly moving spoon towards carrots. Unable to pick up. "Oh dear" Puts head in hands. (Field note, Participant 014, Finger food meal)*

One participant described the finger food as 'the best meal' they had received in hospital, however; this participant continued to highlight the impact of fatigue on the ability to eat a full meal during the finger food intervention. This is illustrated in the following example:

> *047: "That was the best meal I have had in here, but I couldn't eat it all. I get tired, even when eating. I'm going to go to the toilet and then get into bed for a nap." (Field note, Participant 047, Finger food meal)*

The effortful access to meal for some participants was based on the texture of the food. Hard foods, taking increased time or effort to eat, caused participants to stop or give up with eating. This occurred over both standard and finger food observations, despite participants taking part in this study being appropriate to be able to manage regular textured food. Examples from two participant observation are presented below:

> *047 calls over researcher: "I've made a mistake with this; I can't eat any more of it. I shouldn't have really agreed to take part as there are a lot of things that I can't have…I have eaten all of the fruit, so I am OK. It's not too hard, just takes a long time to eat" (talking about cheese toasty) (Fieldnote, Participant 047, Finger food meal)*

> *080 says that she is not really enjoying it and that the meat is very chewy. Says should have got something else. (Field note, Participant 080, Standard meal)*

Effortful access to finger foods were noted by participants where food was difficult for participants to pick up with their hands. This is demonstrated by an exert from the following field note:

> *"These peaches are slippery and difficult to pick up." Attempting to pick up with spoon. "It's difficult catching it, I'll have to ask for different peaches next time." (Field note, Participant 040, Finger food meal)*

Effortful access to the finger foods appeared to be attributed to the impairments caused by stroke such as fatigue and physical difficulties and to the attributes of the food. Participants were observed to report that they would avoid food that was too chewy and hard to eat in the future.

5.6.5.1.2 Variations to finger food access

Participants with preserved motor skills, and who successfully used cutlery for standard meals, continued to use cutlery to access finger food. For these participants, finger foods provided additional menu options but did not alter their approach to accessing the meal.

> *Eating main meal with knife and fork. Pushing food onto fork with knife. Looking around. Puts knife and fork down. (Field note, Participant 059, Standard meal)*
>
> *All patients eating in bay. None requiring support, set up has been completed. 059 cuts potato with knife and fork. Pushing potato onto fork with knife. No difficulties using cutlery. (Field note, Participant 059, Finger food meal)*

Using foods that did not require cutlery was verbalised by one participant as 'easier' and was particularly helpful for participants who had lost full motor control of one upper limb. Finger food was pre-prepared and designed to be ready for eating which enabled some participants to use their hands to eat. Such food also provided increased control for participants to manipulate finger food, including being able to 'dip' food into sauces independently.

> *007 pulls apart toastie with both hands. Cheese very stringy. Daughter laughs. 007: "It's easier than navigating a knife and fork." (Field note, Participant 007, Finger food meal)*
>
> *Eating with right hand. Left hand rests on lap – 064 not attempting to use left hand. Takes bite of potato quarter and picks up pizza slice. (Field note, Participant 064, Finger food meal)*

Most participants used a combination of hands and cutlery to access finger foods. Fingers were used to push food onto cutlery and then transfer to the mouth. Alternatively, hands and fork or spoon were used to transfer food from the plate to the mouth. Providing cutlery with all meal trays, regardless of what was served, supported the flexible access.

> *Using fingers to help scoop food onto fork – plate has no sides so makes putting food onto fork more difficult. Pushes broccoli back onto plate with fingers. (Field note, Participant 006, Finger food meal)*

Although finger food provided was designed to be eaten with the hands only, observations show that participants used both their hands and cutlery to access the meals. Cutlery was placed on trays as 'standard' practice, which enabled this flexible access.

5.6.5.1.3 Enabling independent meal access

Some participants observed displayed a desire to be independent with eating, rejecting assistance from others. For some participants, finger foods supported independent meal access. This meant that assistance from staff or relatives was not required and participants gained control over the pace of eating and choice of food. For example, the field note below shows one participant who was only able to eat small amounts using cutlery with the standard meal. During the finger food meal, the same participant has more control over speed and choice of food moving from main meal to dessert options.

> *Patient in bed G5 talking to 080: "You'll never get fat if you don't eat your food" 080 eating small spoonful's of ice cream, pot is on table, wobbling every time 080 uses right hand only to scoop ice cream out. (Field note, participant 080, Standard meal)*
>
> *Picks up biscuit and eats with biscuit in right hand. Picks up chicken goujon in right hand. Takes bite of chicken goujon. Cuts piece of cheese off with knife. Picks up and eats. Picking food out of teeth. (Field note, Participant 080, Finger food meal)*

Eating finger foods independently meant that one participant took over one hour to finish the meal. The quote below demonstrates that the participant was able to independently access the finger food with no staff support.

> *014 reaching towards plate. Plate slightly out of reach. 014 picks up potato half. Feeds self. All of potato put in mouth. (Field note, Participant 014, Finger food meal)*

This compared to a quote from the standard meal observation for the same participant who required consistent prompting and full feeding.

> *014 to HCA "014 are you going to have your ice cream?" 014 wakes up and looks at table. HCA takes off lid. 014 picks up pot.*
> *014 puts finger in pot and brings finger to mouth. 014 holding pot. Brings pot to mouth to drink.*

> *HCA to 014 "you gonna use your spoon" "have a small spoon" HCA gets small spoon and puts it in the pot.*
> *014 Falling asleep, Pot of ice-cream with spoon in hand.*
> *HCA to 014: "Are you gonna eat your ice cream?" "You want me to help you. HCA supports 014 to feed fully. All ice cream eaten. "There you go beautiful well done." (Field note, Participant 014, Standard meal)*

Finger foods generally provided an option for participants to be more independent with their eating; however, assistance from staff or visitors remained vital to support meal set up.

5.6.5.1.4 Assistance to support finger food access

Assistance over mealtimes was provided by both staff and relatives. Despite participants' desire to eat independently, some were unable to independently access some of the menu items served as finger food. For example, independently opening packaging of some items was a challenge. In these circumstances, ward staff and relatives provided physical assistance for preparation of meals, typically completing the task for the participant.

> *028 attempts to open package of biscuits; however, finds it too difficult. Asks staff nurse nearby to open. As the nurse was trying to open, she crushed all of the biscuit inside (Fieldnote, Participant 028, Finger food meal)*

Assistance throughout the mealtime from staff or relatives was required for participants with perceptual impairments, regardless of whether they were receiving the standard meal or finger food meal. Symptoms of perceptual impairment affecting eating after stroke consisted of visual difficulties recognising objects or difficulties recognising objects by touch as well as limited spatial awareness or inattention or neglect to one side. For participants with perceptual deficits, the provision of finger foods meant that the method of assistance could be offered in the least invasive way. This supported participants to have optimal independence when eating. In this example, the pre-prepared finger food meant that a verbal prompt from the staff was all that was required to support the participant to continue eating.

> *014 HCA "014 are you going to have your ice cream?" 014 wakes up and looks at table. HCA takes off lid. 014 picks up pot.*
> *014 puts finger in pot and brings finger to mouth. 014 holding pot. Brings pot to mouth to drink. 014 Brings pot to lip to drink ice cream. Attempting to drink from the pot. (Field note, Participant 014, Standard meal)*

> *040 sat back in chair. SN comes over to 040. Starts to reposition bed sheets. "Do you want your cake?" Finds cake in bed. "It looks like it's fallen off your table." 040: "Oh yes I was looking for that, I couldn't find it" SN: "It's already been sliced up for you, so I'll just leave it here." (Field note, Participant 040, Finger food meal)*

Ongoing assistance throughout the meal, such as verbal or visual prompting from staff or visitors, was required to support participants with cognitive impairment to remain on task or to initiate eating. Cognitive access for eating reflects the ability to initiate and execute cognitive processes required to engage in the eating process. Cognitive access was reflected in field notes as difficulties initiating or maintaining attention to the mealtime task. Finger foods alone did not appear to support cognitive access.

> *Visitor: "Have you had enough of that?" Points to the plate. 080 Picks up the sausage roll and takes a bite. (Field note, Participant 080, Finger food meal)*

Participants levels of cognitive impairment varied. Participants with increased cognitive deficits tended to require more input from staff or relatives over mealtimes. The quote below presents an example of where staff provided a model of how to use hands to eat the food.

> *HCA "You can use your hands If you prefer" 071: Appears confused by using hands: "What do you mean" HCA1: "I can show you." Uses hand over hand facilitation to pick up pizza slice with left hand. (Field note, Participant 071, Finger food meal)*

The presence of a close family member over mealtimes supported individualised meal preparation. Access to the meal was enabled by family members reinforcing participant preferences and strategies previously employed by family prior to their hospital admission. Generally, these were not strategies acknowledged by members of staff but used when family members were present.

> *"Problem is there is so much meat in the sandwiches she finds it difficult to chew". Visitor had set up tray, removed sandwich crusts and some ham inside sandwich and put on plate. (Field notes, Participant 018, Finger food meal)*

Finger foods did help participants to be independent with eating, if foods were easier to eat and not too chewy. There was a range of findings: some participants were able to access finger foods by using both their hands and cutlery; some continued to require support from staff or relatives with meal set up, regular prompting and enabling habits and preferences to be known. Observing the differences in how the finger food was used in practice and engaged with by participants provides important insights for a future trial.

5.6.5.2 **Meal quality**

Influences of meal quality on food intake is described by the M3 model as the sensory appeal, nutrient density, variety and preference, presentation and food safety (Keller et al. 2014). Limited regard to meal quality was provided in field notes, however finger foods were noticed as 'different'.

5.6.5.2.1 Noticing finger food as different

Members of staff commented on the finger food as different, singling out participants trialling the finger food. Awareness of the finger food and purpose of providing it varied between members of staff, some suggesting it was provided as a ‘treat’ as opposed to a supportive intervention. Most of the time, field notes showed that finger foods on the wards sparked interaction between members of staff and participants. This is illustrated in the following quotes:

> *SN comes over: “Oh you’ve got a cheese toastie. Yum. How did you wangle that one!” (Field note, Participant 007, Finger food meal)*
>
> *New HCA comes on shift. HCA1 to HCA2: “Look she’s got a pizza I’m so jealous!” 033 smiles. HCA’s and visitor to O3 talk about different pizza toppings. “She’s on the finger food menu” (Field note, Participant 033, Finger food meal)*

Observing the reactions from members of staff towards the finger foods also had the potential to impact on meal experience and the social engagement between patients and staff.

5.6.5.3 **Meal experience**

Using finger foods impacted on meal experience by sometimes providing participants with foods that were easier to manage and therefore caused less spilling and enabled improved experience of the meal. It enabled them to have control over the pace of the meal, increasing their desire to eat food they wanted. For others their experience of having finger foods was impacted on by the beliefs of others around them, enabling or disabling them to eat with their hands. Staff often commented on the use of hands in relation to their own views; this either supported or disabled participants willingness to use their hands to eat the food depending on their own background and beliefs.

Keller et al. (2014) describe meal experience as the third aspect directly influencing food intake and incorporates social interaction, ambience, meal pace, appetite and desire to eat. The experience of finger food in hospital was impacted upon by participants perceptions of their eating difficulties and how others around them reacted to this, described as ‘embarrassment of lacking control’.

5.6.5.3.1 The embarrassment of lacking control

Mealtime experiences were impacted on by the amount of control the participants had with eating. Participants expressed concerns about spilling food or making a mess across standard meal observations and during the trial of the finger food meal. Participants were observed to drop cutlery, plate lids and other items from their table, which were often crowded with personal and medical equipment as well as lunch trays. Participants were also observed with food spread across their face as a result of un-coordinated transfer of food from the plate to the mouth. This is illustrated below:

> *007 Eating with spoon in left hand. Nearly drops the pot. Manages to partly save it. Grabs pot between hands and body. "Oh damn" Visitor looks over. 007: "I am being a mucky pup again." …007 aloud: "Thought it was too good to be true, I was doing quite well then." No staff in bay. (Field note, Participant 007, Standard meal)*
>
> *Ward Host to 064: "Are you enjoying that?" 064 puts thumbs up. Ward Host: "You look like it" Ward Host makes a comment about food being all around his face.(Field note, Participant 054, Finger food meal)*

Some participants had expectations that finger foods would be easier to control and expected a reduced amount of 'mess':

> *007 talking to daughter at bedside: "I am having the finger food diet today. Hopefully it means that I don't throw my food around so much" Daughter: "Oh yes that's what happened with that salad last night" (Field note, Participant 007, Finger food meal)*

However, for participants with more severe eating difficulties the provision of finger food did not totally eradicate mess and dropping food. This one example shows the participant explaining the embarrassment of dropping food and the effect of losing control.

> *Drops some food on lap. 028: Looks over to SN "My mouth is in the wrong direction, it's awful when you used to have control of the whole thing and it goes" (Field note, Participant 028, Finger food meal)*

For some participants, using their hands to eat caused increased mess and increased requirement for staff assistance to clean faces and hands. Awareness of messy eating was deemed as 'child-like' by another patient in the bay, who joked about the participant making a mess.

> *Health care assistant walks towards 064: "Do you want a tissue? You have got it everywhere" Health care assistant opens wipes and passes them to 064, gesturing where he needs to wipe his mouth. G4 shouts out "You need a highchair too. You've missed a bit on the top of your head." Laughing. (Field note, Participant 064, Finger food meal)*

For other participants, wiping their hands and mouth and clearing up could be achieved more independently. When staff prompted participants to use a 'wet hand wipe' provided with all meals, participants frequently declined and chose to either 'lick their fingers' or wipe hands using a napkin or serviette provided. In many cases, staff anticipated mess would be made by providing participants with plastic aprons, typically used by staff for infection prevention measures.

> *Staff nurse prompting 042 to use hand wipe – 042 declines. Staff nurse provides 042 with apron. (Field note, Participant 042, Finger food menu).*

> *Husband points out that 095 has not wiped her mouth on the left side. 095 apologises that she missed it and wipes with the serviette. (Fieldnote, Participant 095, Finger food menu)*

The control with eating appeared a major theme from field note observations. Participants were explicit when describing that they had lost control with eating. Finger foods attempted to support control and independence with eating but also meant that support with clearing up was required.

5.6.5.4 **Hospital system**

The overall theme of the 'hospital system' captured external factors which impacted on how finger foods were served and used within the hospital. This includes logistical demands of the new menu which differed from the standard procedures. These factors could not necessarily be altered at ward level but as part of a higher-systems level approach.

External factors described include a paradox between a time-restricted, un-prioritised hospital mealtime verses a flexible finger food intervention which was evaluated. In addition, this theme captures thoughts on staff influence on how finger foods were perceived.

5.6.5.4.1 Using finger foods within a time-bound mealtime task

Ward hosts were responsible for controlling times that meals were served, delivering, and clearing meal trays. Typically, this occurred at the same time for all patients in a bay, regardless of when their meal was served and whether they had finished eating. Finger foods were required to fit with the current time-bound mealtime task, despite different cooking mechanisms delaying when the finger foods were served. This is illustrated in the quote below:

> *Ward Host enters and asks if participant has finished. Suggests she will take the main plate and tray. 028 asks to leave the peaches and cheese and biscuits as she has not yet finished with that yet. Finishes peaches and picks up biscuits and cheese. Realises these have not been put on a plate and that her plate has been taken away. Asks HCA to get a small plate from the kitchen. (Field note, Participant 028, Finger food meal)*

For some participants, the time taken to eat finger food was longer than the standard meal. In one field note example this impacted on therapy tasks and the participant was hoisted back into bed partway during the meal. The paradox of time here is acknowledged, where despite therapists saying, 'take your time', the participant is forced to eat around the time-based task. It took 30 minutes to hoist the participant back into bed; however, finger foods were continued to be consumed when the participant was back in bed.

> *014 Looking up. Visitor walks into bay. Physiotherapist comes back into bay. Talking with staff nurse: "014 has been out of bed for 30 minutes and needs to go back in due to pressure sores". Physio talks with 014 "Have you finished your lunch?" 014:"No" Physio: "I'll go and get you the hoist and leave you to finish your lunch. I'll be back in two minutes" 014 looks teary – "Take your time" (Field note, Participant 014, Finger food meal)*

5.6.5.4.2 Flexibility of finger food in un-prioritised mealtime

The flexibility of the finger foods intervention enabled food to be eaten during mealtimes that were frequently interrupted by medical tasks on the ward such as medication rounds and visits from other professionals. These interruptions were sometimes of detriment to the food quality, however where finger food was served cold, this allowed participants to carry on eating.

> *Phlebotomist walks in towards 007. "I've come to take some blood, but I can see you are still eating. I can come back if you want?" 007: "No you can take it now, thank you" Phlebotomist agrees and sits down next to 007. Prepares arm. Talking to phlebotomist and continues to eat sandwich with other hand. (Field note, Participant 007, Finger food meal)*

Documentation tasks such as completing food record charts and computer records were observed to be prioritised by staff over supporting patients with lunchtime meals. Participants were observed to be supported with meals after documentation tasks were completed. For standard meals, often food was sitting around for prolonged period before being accessed by the participant. The participants could have avoided delays to eating if appropriate access and staff support was provided. For some participants finger foods provided the ability to begin eating straight away. The comparison between a standard mealtime and finger food meal observation is illustrated below:

> *Staff Nurse to 014 "I'm going to help you with your food in a moment ok" Opens lid on food. "Shall I get you an apron?" Goes to get blue plastic apron and puts on 014. Moves table closer and gives fork and spoon to patient. 014 holding spoon in left hand and fork in right hand. Staff Nurse leaves to return to computer (Field note, 014, standard meal)*
>
> *040 picks up fish finger and eats straight away. 040: "Look at that I'm going straight away!" (Field note, Participant 040, Finger food meal)*

During all observations, meals were served at the bedside with no other option provided for participants to eat elsewhere. There were no separate dining areas on the study ward or communal tables for eating within the bay. Participants who were not independently mobile were required to eat either in their chair or in bed where they had been situated previously and requested to stay there until the mealtime was over. Participants who were mobile had more flexibility of independently moving from their bed into their chair or vice versa for meals.

> *031 calls Staff Nurse telling her she needs to go to the toilet. Staff Nurse asks if she can wait until after her lunch. She agrees. (Field note, Participant 031, Finger food meal)*

Priorities within the hospital system such as risk of falls, meant high staff distress was caused when participants attempted to move from their original eating position. This reflected on the participants, causing disengagement with eating. Despite finger food meal described by some as food that can be eaten 'on the go' (Crawley and Hocking 2011), inflexibility of ward policies and procedures made this challenging.

> *071 moves table around. Sandwich nearly falls off table. Attempts to stand up from chair. Staff Nurse rushes over from medicine trolley. Staff Nurse: "Sit on chair, you need to sit down, you have got your lunch here. Can you hold the sandwich? It's with ham". Staff Nurse passes 071 quarter of sandwich. Staff Nurse: "It's nice"*
> *071 has finished eating sandwich quarter. Attempts to stand up from the chair. Staff Nurse rushes straight over to 071. "Oh here, 071 here's your sandwich. 071: "What's it for?" Staff Nurse: "It's your sandwich, you can eat it" Staff Nurse: Raising voice "Eat it please" 071: "No I don't like being told… SN: "Eat your lunch please, you just had one of those sandwiches"071: "I don't know". "No, I don't want it" (Field note, Participant 071, Finger food meal)*

In some ways, the flexibility of the finger food intervention supported fit within hospital mealtimes that were frequently interrupted by medical tasks. They provided a flexible option for participants to eat small amounts more regularly. However, the culture and current structure of the hospital system impacted on the ability to fully utilise potential opportunities for using finger foods flexibly.

5.6.5.4.3 Staff influencing beliefs about using fingers to eat

Staff members verbalised their own beliefs regarding whether food should be eaten with the hands, depending on their own backgrounds and experiences. The field note example below shows as extract between two members of staff joking about their own eating habits.

> *Ward Host enters with the tea trolley. Staff Nurse and Ward Host joke about eating pizza with hands. Ward Host explains she always eats it with a knife a fork. SN explains its finger food it's meant to be eaten with the hands! (Field note, Participant 091, Finger food meal)*

Some participants looked to staff for reassurance about whether they could use their hands to eat. This is illustrated in the following:

> *Ward Host puts tray down. Here's the pizza. 018: "Can I use my fingers?" Unable to hear response. (Field note, Participant 018, Finger food meal)*

The beliefs of staff members impacted on participant's access to food. Members of staff who were used to using their hands provided reassurance to participants and prompting them to use their hands to eat.

> *091 Picks up knife in right hand and starts stabbing at pizza in attempt to cut it. Having difficulty cutting. … SN approaches 091's bedside. "It's a pizza; you can eat that with your fingers!" "I'll clean them up after" 091 picks up pizza with right hand.(Field note, Participant 091, Finger food meal)*

Other members of staff acknowledged that eating with hands was different for everyone and observed that the participant eating 'mushy food' with one utensil was 'easier'.

> *014 Reaches towards fish with left hand. Licks thumb on right hand. SN looks towards researcher, speaking "I think she finds it easier with cutlery. She seems to be chasing food around the plate. When she has cottage pie or mushy food is able to eat with a spoon. It's funny because I would have thought would have been easier with finger food, guess it's different for everyone." (Field note, Participant 014, Standard meal).*

Other comments made by a member of staff about a participant on the ward, suggested that it was unacceptable to eat some foods with the hands.

> *HCA goes back to feeding G2. HCA talking with researcher: "She is very slow, she was just trying to eat with her hands, so I have to help her (had cottage pie)." (Field note, Participant 037, Standard meal).*

Staff members supporting participants on the ward had their own views and beliefs on eating with the hands. Some supported the behaviour and others suggesting using a cutlery is 'better'. Experiences of using hands to eat were further explored in semi-structured interviews.

5.6.5.5 **Development of intervention**

It was important to understand how the finger food intervention was used on the ward and to consider necessary future developments. This domain supported key themes generated to understand how finger foods could be implemented within different contexts for example ward environments. This includes considerations to time for food preparation and special food requests.

5.6.5.5.1 Time for food preparation

Finger foods required additional preparation on the ward, which was expected to fit with the current scheduling of the mealtime routine. Typically, ward hosts and the housekeeper or healthcare assistant supporting the meal tray delivery ensured that the tray was on the participants table and in reach. However, it was the responsibility of nursing staff in the bay to prepare food for consumption.

Memos show the PhD candidate was required on some occasions to support with the meal preparation or prompt the catering team to present food appropriately to be eaten with the hands. For example, peaches in juice were provided in a small pot which was difficult to open. Despite this, it could be served as finger food in a bowl with the juice removed.

> *Fruit wedges ordered up – apple cut up and put in a tray – core not removed, irregular pieces, WH refuses to serve due to poor presentation (Field note, Participant 084, Finger food meal)*
>
> *Researcher had to support ward host to cut up fruit and cut to prepare roll (Field note, Participant 013, Finger food meal)*

When the PhD candidate was not available, finger foods were served to participants without being fully prepared. This meant they did not meet participant's expectation of finger foods.

> *"It's meant to be fish finger but it's very large. Visitor: "Largest fish finger ever." (Field note, Participant 045, Finger food meal)*

There was evidence of meal serving delays with the serving of finger foods, due to different cooking mechanisms. This became a challenge where an agency ward host, not used to working on the wards and not aware of procedures, was deployed onto the ward.

> *Pizza was cooked incorrectly, therefore had to be re-ordered up to the ward. (Field note, Participant 018, Finger food meal)*
>
> *Meal tray delivered slightly later that the others as 007 was having cheese toastie that requires alternative cooking. (Fieldnote, Participant 007, Finger food)*

5.6.5.5.2 Special requests and familiarity of food

Familiar foods which participants had been having since admission to the ward were often requested to be ordered alongside food from the finger food menu. These included ice-cream and custard served in a bowl. This meant during observations of finger food meals, participants were served sides or desserts considered 'standard food'.

> *003 Eating ice-cream, spoon in right hand. Holding pot in left hand. (Field note, Participant 003, Finger food meal)*

Participants commented that they chose food they were used to having at home adding a sense of enjoyment or relishing back to previous experiences of enjoying this food. For some the finger food had been part of their daily routine and was something familiar to come back to. This is illustrated by the following quote:

> *StN starts to fill in food charts for 057. 057: "I have this sometimes when I go to town!" (Field note, Participant 057, Finger food meal)*

There were examples where participants requested smaller portions of food to fit in with their usual mealtime routines. The importance of the presentation of the food and how it was served was highlighted here.

> *Meal tray delivered, "012, there's your lunch here." 012: "I hope it's not too much; I don't like eating much at this time of day" (Field note, Participant 012, Finger food menu)*

The finger food menu in the trial was observed to be offered flexibly with other standard items at request of participants. Familiarity of food and routines was observed to be of importance to participants who tried to replicate home eating habits.

5.6.5.6 **Summary of mealtime observation data to assess feasibility of intervention delivery**

Findings from observations revealed the importance of attending to patient factors as well as system factors to ensure successful implementation of a finger food menu within the hospital context.

Participants' access to the finger food was influenced by their motor, perceptual and cognitive abilities. Access to the finger food meal varied for each participant, dependent on their level of motor, physical and cognitive access, and ranged from eating a full finger food meal with the hands, using both hands and cutlery to eat and using a knife and fork for the full finger food meal. Where participants used their hands in place of cutlery, they were provided with control over speed and food choices.

The presentation of food impacted on whether participants were able to access the food independently. For participants with motor, perceptual and cognitive access impairments, participants continued to require assistance from staff or relatives to open packaging or prepare foods to be eaten with the hands. Participants were embarrassed to spill food and cause mess and perceived finger foods as reducing this mess. However, observations showed finger food often required support from staff with clearing up.

Familiar foods were often requested to be ordered alongside food from the finger food menu, attempting to replicate foods from home and requests for smaller portions were made by some. Members of staff commented that the finger food was perceived as different, singling out participants' trialling the finger food. Staff members verbalised their own beliefs regarding whether food should be eaten with the hands, depending on their own backgrounds and experiences, which impacted on food access for participants.

The regimented hospital system provided a barrier to using a flexible approach to serving finger foods; however, the flexibility of finger foods sometimes enabled meals to fit around other tasks.

Finger foods needed additional preparation on the ward, which was required to fit with the current scheduling of the mealtime routine.

To further develop the intervention for a future trial and support success in delivery, consideration should be given to training staff for preparing, serving and supervising meals and to developing menus with input from patients.

5.7 Facilitators and barriers to the intervention delivery

The findings presented from mealtime observations provided information about how the intervention was delivered on the ward. These findings, describing the intervention delivery, can be mapped to the concepts of the I-PARIHS framework (Harvey and Kitson 2015b). In this way the principles of implementation science within this feasibility study were able to be considered in a structured way and the barriers or facilitators encountered could be described. Based on these, strategies to support implementation could be identified and used as part of the design of a future intervention study to introduce a finger food menu.

As further described in section 3.4.5, the I-PARIHS framework emphasises the strength of each of the following components: the innovation and evidence base that supports it, the context in which the intervention is implemented, the facilitation used to support implementation and recipients of the intervention (Harvey and Kitson 2015b). Mapping findings from this feasibility study to the framework further describes how the innovation or evidence base for the trial was perceived by staff and patients, which characteristics of the context impeded or facilitated implementation, and which tools and support facilitated dealing with identified barriers. These factors are relevant to consider promoting implementation success in a follow-up trial (see Table 5-12)

The I-PARIHS concepts considered within this stage of the feasibility study are explored below:

- Innovation – This element relates to the strength and extent of evidence for clinical practice changes and includes evidence from clinical practice, perceived patient needs and preferences, and local data/information (Harvey and Kitson 2015b).
- Context – This element refers to the environment or setting in which people receive healthcare services or the context in getting research into practice (Harvey and Kitson 2015b). The context is deemed important in a number of implementation frameworks and would develop understanding of setting related barriers or facilitators.
- Facilitation – This element is defined as an appointed role wherein an individual helps and enables others to change and defined as the active ingredient to implementation success

(Harvey and Kitson 2015b). This element was felt to be essential to implementation success in this feasibility study and therefore it was important to understand in more detail what facilitated the intervention success, including the role of the facilitator and processes that supported facilitation.

- Recipients – This concept highlights the motivation, values, and beliefs of groups and recipients of the intervention (Harvey and Kitson 2015b). The opinions and acceptability of finger foods were further discussed in interviews with participants and members of staff and therefore not considered within Table 5-12.

Table 5-12 Facilitators and barriers to implementation and suggestions to enhance implementation in a future study

I-PARIHS determinant	**Facilitator/barrier described in the feasibility study**	**Suggestions to enhance implementation efforts in a future study**
Context	Hospital mealtimes are restricted by time constraints. Finger food meals can take an increased length of time to consume.	Ensure resources are available to account for longer eating durations, including flexible serving and collection times.
	The inflexibility of ward policies meant that finger foods were not always used as intended. For example, nursing staff encouraged participants to be seated whilst eating and did not allow participants to eat as they wandered around the ward.	Develop the intervention in line with other hospital policies. Provide training to staff to determine how the intervention fits with other policies.
	Staff members' beliefs about whether food should be eaten with their hands was based on their backgrounds and experiences. This influenced the behaviour of participants who were patients and whether they felt comfortable using their hands to eat.	Engage all staff early, particularly clinical and frontline staff, to understand and address concerns about using the menu in their ward.
	Provision of ward training for catering staff meant adding a new menu did not result in any added complications for meal ordering.	Engage key leaders to ensure that training can be provided so that the new menu fits within the current systems.

I-PARIHS determinant	**Facilitator/barrier described in the feasibility study**	**Suggestions to enhance implementation efforts in a future study**
	Some participants chose not to order from the finger food menu because the menu was only offered over lunchtime meals. Offering the menu at only one mealtime has the potential to limit recruitment and impact data collection in a future trial.	Develop a menu with items that can be offered over multiple mealtimes to support participation.
Facilitation	Availability of the researcher on the ward meant that ward hosts could be reminded about the required presentation of the finger food, for example, to open the packaging and cut fruit into wedges. The availability of the researcher supported the staff to adopt change into practice. If new members of staff or agency staff were working on the ward, the researcher provided information about the new menu.	Train a formal leader to support the delivery of the food and to ensure they are available over mealtimes.
	The availability of the researcher, who was known to ward staff and had links with key leaders, supported the adoption and adaption of the menu to meet special requests. For example, allowing the finger food menu to be offered flexibly with other standard items at request of participants.	Ensure the formal leader works closely with staff and is available to understand the barriers to implementation. The formal leader requires problem-solving and leadership skills to be able to support adaptions of the menu.

I-PARIHS determinant	Facilitator/barrier described in the feasibility study	Suggestions to enhance implementation efforts in a future study
Innovation	Participants reported that, theoretically, finger foods would give them more control over their eating and would reduce the amount of 'mess' made when eating. These views meant participants were interested in trying the finger food items. In practical terms, some participants required help from staff to clear up after eating finger food.	Incorporate PPI in testing suitable items for the finger food menu. PPI will help ensure menu items are practical to use on the ward for the population of interest. Incorporate views of a diverse group of patients and the public to encapsulate a range of views. Incorporate views of PPI representatives in the design of the trial and information sheets to inform potential participants about how finger foods should be used.
	Staff showed awareness that the finger food was different but were not necessarily aware of the strength of evidence relating to the intervention of the evidence base or reason behind using the food.	Engage all staff early, including clinical staff, to understand the reason for using finger foods on the ward.

5.8 Adverse events

There were no adverse events or harm to patients or staff recorded during this study.

5.9 Future sample size

One of the key objectives of this feasibility study was to estimate a sample size for a future trial. It is recognised that both underpowered and overpowered trials are unfavourable for any study and present problems with regards to ethical decisions, statistical and practical challenges (Teare et al. 2014).

To determine a future sample size, initially a clinically significant change in energy intake needs to be established. Based on the results of this feasibility study, which used a small sample size of 19 participants, it is unknown whether a finger food menu can produce a clinically significant increase in energy consumption, and this is what a future trial should aim to establish. Therefore, estimates for a significant change in energy intake are proposed considering information collected from this feasibility study.

A future sample size estimate for this study is made on the basis of a 25% increase in energy being clinically significant. Based on results from this feasibility study, this provides an absolute difference of 113kcal per meal, using a standardised effect size of 0.47 and the largest pooled standard deviation of 240.6, which corresponds to day three (finger food meal) compared to baseline (standard meal). This estimate could be likely, given this feasibility study showed an increase of 149kcal over a lunchtime meal when the finger food menu was implemented. Similar estimates of clinically sufficient increase in energy have been reported by Roberts et al. (2013). The mealtime assistance study evaluated the effect of volunteer support on energy intake of hospitalised older adults and suggested a clinically sufficient difference in energy intake to be 218kcal per day, with 80% power and $p<0.05$ (Roberts et al. 2013). This was based upon a mean intake of 1300kcal (SD 550) per day. A clinically sufficient difference of 218kcal per day would suggest an approximate increase in energy of 73kcal per meal, based on 3 meals a day.

Based on robust estimates from this feasibility study, with energy intake being a primary outcome, a minimum sample size of 330 participants is proposed (165 in each arm of the trial). This is based on a two-sided test at a 5% significance level. This sample size will provide 90% power (National Institute for Health Research - Research Design Service 2020) to detect an improvement of 25% in energy intake having the finger food menu compared to the standard menu and allowing for 40% loss to follow-up. If the effect size is changed the total number of patients would be approximately 790 (to detect a 15% change from baseline) and 450 (to detect a 20% change from baseline). These sample size calculations assume a two-sided test at 5% significance level, 90% power and 40% anticipated drop-out rate.

This number is an estimate, and a future sample size will need to consider other factors which may influence sample size required. These include funding available, researcher time, analysis considered and study design. For example, the number of participants required may require inflation considering the type of ward and size of wards used in a future study. It may be necessary to multiply the sample size by an inflation factor to look for differences across groups, to have a better coverage and make more comparisons of sufficient power to make proper estimates.

If a future trial takes a different design, such as a cluster trial, with the unit of randomisation being the ward rather than the individual, an inflation for design effect will be justified. This inflation effect can be considered from an estimate of the intraclass correlation (ICC) based upon other studies that have used a cluster randomised control design or an ICC that is adjusted as data are collected.

The design of a future trial would be informed by the results of this feasibility study and a wider team of service users and researchers and draw on current evidence to determine the length of the trial and whether cluster or individual randomisation would be appropriate. An increase in energy intake was observed in this feasibility trial, therefore, a future study should consider a similar design offering a finger food menu for one meal a day for consecutive days. The length of the trial would be dependent upon time and funding available.

5.10 Limitations

Acknowledging the limitations of a feasibility study future proofs designs of prospective research trials. Addressing sources of bias and uncertainties about the intervention enables discovery of limitations that may arise in a future, larger trial (Eldridge et al. 2016a). This section provides key limitations of the current study with corresponding recommendations for a future trial. Each limitation is presented as a statement, with further discussion below.

5.10.1 Sample size

The sample size for this study was small, meaning that statistical tests were limited. This was anticipated during the study design as the primary aim of this study was to assess feasibility and not determine effectiveness of the intervention. The potential for missed effects secondary to the small sample size should be considered during the design of a future larger trial. Using data from this feasibility study will support an adequately powered sample size to be calculated for a future trial with sufficient data collected.

5.10.2 Demographic data

Data collected from hospital admission paperwork was not necessarily an accurate reflection of participant’s level of impairment or nutritional status. To support understanding of the sample population NIHSS (Goldstein and Samsa 1997), BMI, MUST (BAPEN 2016) score and evidence of cognitive impairment were extracted from participants hospital admission paperwork.

Participants had been in hospital for a mean length of 16 days on consent to the study. Levels of impairment and or nutritional status would likely have changed during this time and therefore not accurately reflect the participants' level of impairment during the study. Details of impairment to participants’ cognition was recorded to different levels amongst notes, meaning true level of cognition was difficult to assess for each participant.

It is suggested that future research should consider alternative demographic data collection techniques to support the reliability and accuracy of this information. One recommendation could be to use the MRC power scale recorded on consent to study to support identification of physical impairment to the upper limbs. The scale includes a range from zero to five, with five being maximum power expected for the muscle. The MRC reports that the scale is more reliable and accurate for clinical assessment in weak muscles (grades 0-3) and appropriate for use for people after stroke (John 1984; Medical Research Council 2018). To include the MRC muscle scale score in a future trial, the researcher requires training to undertake this assessment for all participants. An alternative recommendation would be to repeat the NIHSS (Goldstein and Samsa 1997) on enrolment to the study to acknowledge the level of participant disability post-stroke.

A formal assessment of cognition, such as a MoCA assessment, described as a cognitive screening tool validated for detecting mild cognitive impairment with 90% sensitivity (MoCA 2019), could be considered for a future trial for a more consistent recording of cognitive deficits. At present, the PhD candidate is not aware of a gold standard assessment for screening cognitive impairment deficits after stroke, however the MOCA is deemed useful in supporting recognition of deficits (Kosgallana et al. 2019).

5.10.3 Blinding

The inability to blind participants in this study may have introduced bias. Conducting a pragmatic trial on the ward meant it was not possible or ethically viable to blind participants or members of staff to what food participants were eating. It is therefore possible that participants or staff could have consciously or unconsciously changed their behaviours whilst being observed over mealtimes to reflect the anticipations or expectation of the researcher and being involved in the research study. In addition, the PhD candidate was not able to be blinded during dietary intake estimations. She was the only one collecting and analysing data for the small sample, which may have impacted on estimated results.

5.10.4 Randomisation

The study sample was not randomised leading to potential introduction of selection bias. Randomised control trials are the gold standard for assessing intervention effectiveness. Due to the limits of a single ward used for data collection, randomisation was not deemed viable for this feasibility study. However, future research should consider a randomised sample to increase reliability of outcomes and reduce selection bias. Methods of randomisation should be chosen, considering the study setting.

Another option for individual randomisation is cluster randomisation which may be more appropriate considering the high potential of contamination between individuals. Cluster randomised trials typically evaluate complex interventions, with complicated trial logistics (Eldridge et al. 2004). Cluster randomisation has been successfully trialled within feasibility testing of nutritional interventions in six UK care homes, which were randomised by home (Stow et al. 2015). Randomisation at ward level could be used within a future multi-ward or multi-centre trial.

5.10.5 Patient reporting bias

Eligibility to participate in interviews was limited to participants with capacity, potentially causing bias in the sample interviewed. It was not considered ethically viable to interview participants who lacked capacity to personally consent to the study. However, not including this patient group in interviews may have impacted the data collected and not be fully representative of those included in the study. Considering that all participants agreed to take part in the interviews, future studies should look to include further opportunities for participants to provide feedback on their experiences.

5.10.6 Brief intervention period

Participants were involved in the intervention period for a brief period and interviewed only at one time point. Participants trialled the finger food intervention for a maximum of two mealtimes, and staff were intermittently involved in the study based upon their working pattern and the location of participants taking part in the study. Future studies should consider patient and staff views of the intervention prior to involvement and during an additional follow up which would have added depth to the study.

5.10.7 Inclusion of relatives

None of the patient participants' relatives were interviewed for this feasibility study. Despite the protocol indicating that participants could request a relative to be present in the interviews, none of the participants opted for this. The inclusion of relatives' experiences and views would provide further, deeper understanding to the acceptability of finger foods. Views of others, particularly staff in this study, appeared to influence how participants perceived the finger foods. Therefore, the views of relatives, particularly those present at mealtimes, are important to capture.

The inclusion of relatives' views would also provide important data to understand the potential adoption of finger foods for patients once discharged home. Establishing any long-term effects or coping mechanisms for improving intake or independence with eating once discharged. Evaluating whether participants continue to use finger foods trialled in hospital in their home environments would demonstrate the potential for carry over of the intervention.

5.10.8 Accuracy of food composition data

The food composition data were obtained from the hospital caterer to estimate the nutritional composition of each menu item. These values were likely derived from average content values provided by the supplier; however, the accuracy of this data cannot be commented on as the method by which these values were originally obtained is unknown.

5.11 Generalisability

The CONSORT guidelines define generalisability for pilot and feasibility study as the applicability of trial methods and findings for future trials and other studies (Eldridge et al. 2016a). This section reports on considerations of the study setting and participant characteristics which have the potential to limit generalisability.

5.11.1 Setting

The study setting should be fully described to consider effects of generalisability. Participants for this study were recruited from one stroke rehabilitation ward in an NHS hospital on the South coast of England. Previous recommendations and literature have focused on the use of finger foods for people with dementia in long term care settings (Heelan et al. 2019). The results of this study focus on a different setting, providing a new body of evidence regarding the use of finger foods for people after stroke within a hospital.

The ward used for this study employs a dedicated therapy team including SLTs and dietitians who provide specialised advice on swallowing difficulties and nutrition. Members of staff receive enhanced training on supporting people at mealtimes. Due to the high prevalence of swallowing difficulties in people after stroke, all patients are screened for signs of dysphagia on admission. This meant the staff on the ward were well trained to respond to signs and symptoms of dysphagia and had prior training and specialist input on swallowing difficulties and nutrition. This high level of nutrition awareness may not necessarily represent a typical hospital ward in different areas of the hospital and therefore limits generalisability to other wards.

5.11.2 Stroke severity

The study sample included participants mostly with mild to moderate strokes according to NIHSS scores. This could have been partly influenced by the strict eligibility criteria used to include only participants able to manage a regular textured diet (IDDSI level 7). This would have inadvertently caused a pull in selection towards patients with less severe strokes, less likely to have swallowing difficulties. In addition, participants were mostly recruited from bays further from the nurses' station, and likely further along in their rehabilitation and with increased levels of independence, which would limit the variation in sample.

5.11.3 Nutritional status

The BMI of the study sample recorded on admission to hospital were mostly of healthy nutritional status on admission. A high number of participants classified as 'overweight' based on their MUST score remained in the study across all three days. This did not represent other literature in this area, which indicates that 29% of patients are classified as being at risk of malnutrition on admission to a UK hospital (Russell and Elia 2014). The small sample used for this study may not be a typical representation of all patients admitted to hospital.

5.11.4 Ethnicity of participants

Ethnicity of participants was not reported in this study. Therefore, true ethnic demographics of participants were unknown. Interpreters were not provided, and this limited recruitment to patients who were able to understand English. In a future study, particularly if conducting a study in a context where there is wide ethical diversity, it will be important to use interpreters to support the recruitment process. Catering for patients from various ethnic backgrounds should also be a consideration in creating the finger food menu. The menu provided for this study repurposed food items already available and procured for use in the hospital. In a future study consideration to the study context and diversity of participants should be addressed to ensure the menu items represent the population it is providing to. This will include close working with clinical, catering and patient and public representatives to understand the context for the study.

5.12 Chapter conclusion

This chapter has displayed results in terms of the study processes for each of the pre-specified feasibility objectives (trial design, conduct and processes; measures; outcomes and intervention content and delivery). Findings from both quantitative data collection and qualitative field notes provided important information about the practicalities of conducting the study and using the intervention on the ward. Highlighting the limitations to this study, supported important recommendations for a future study to be made.

To explore these ideas further and truly understand the experiences of those who participated, findings from qualitative interviews of participants who were patients and staff are presented in the following chapter. The interviews explored the acceptability of the intervention, an important part of the feasibility testing. Sekhon et al. (2017) suggest that patients are more likely to adhere to treatment recommendations, and benefit from improved outcomes, if the intervention is deemed acceptable. In addition, evaluating acceptability can support adaptations to the intervention to ensure optimal effectiveness in a future trial.

Chapter 6 **Acceptability of the intervention**

6.1 Introduction

This chapter presents the findings from the qualitative interviews used to explore participants' experiences and perceptions of the intervention. Twelve members of staff and eleven participants who were patients involved in the study were recruited by purposive sampling. Findings are presented as themes generated from reflexive thematic analysis.

6.2 Participants

This section provides details of the participant characteristics for both the patient and staff groups interviewed.

6.2.1 Participant characteristics - patients

In total, twelve patients were interviewed. Table 6-1 describes characteristics of patients interviewed. Participants were approached to take part as they had characteristics that would support explanation of the quantitative results. There was an equal split of males and females, with a range of ages (65-90 years) and a range of stroke severity score (scored at admission). Four participants interviewed declined trialling options from the finger food menu over two lunchtimes when the finger food menu was offered, which provided a range of views.

Table 6-1 Characteristics of patients interviewed

Participant ID	Age	Male or female
095	67	Female
091	76	Male
084	70	Male
080	65	Female
077	83	Male
057	66	Male
056	82	Female
055	82	Male
037	90	Female
018	86	Female
006	84	Male
003	89	Female

6.2.2 Participant characteristics - staff

Eleven staff members were interviewed. Staff members were purposively selected to include diverse roles including members from catering team and ward staff. Table 6-2 describes staff characteristics.

Table 6-2 Characteristics of staff interviewed

Participant ID	Role	NHS Band	Years of experience
023	Dietitian	7	1 year
086	Dietitian	7	15 years
026	Health Care Assistant	4	1.5 years
066	Health Care Assistant	4	6 years
094	Health Care Assistant	4	5 years
072	Occupational Therapist	6	2 years

Participant ID	Role	NHS Band	Years of experience
093	Speech and Language Therapist	6	2 years
067	Staff Nurse	5	15 months
083	Staff Nurse	5	11 months
100	Student Nurse	N/A	17 weeks
24	Ward Host	N/A	13 years

6.3 Data analysis

Patient and staff interview transcripts were analysed separately, before comparing and contrasting them to generate final themes. There was an overlap in themes generated from patients and staff, therefore in phase 4 of the reflexive thematic analysis process (section 4.10.2 page 127), themes were amalgamated and presented here as one data set. Contrasts and comparisons between views and experiences of the patients and staff interviewed are made.

6.4 Interview themes

Themes generated from reflexive thematic analysis are presented in Figure 6-1. The figure displays four main themes generated which are deemed fundamental in the acceptability of the foods on the wards. There is an additional theme ‘engagement of participants’, which provides contextual information. Each theme requires careful consideration before launching into a protocol for a future trial. Each theme is divided into subthemes and provided with narration and quotes extracted from interview transcripts. Quotes from both patients and staff who were interviewed are reported throughout all themes.

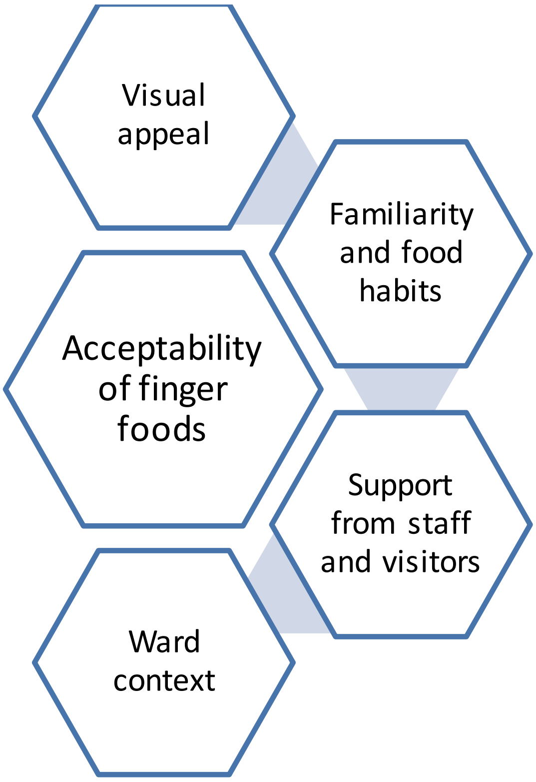


Figure 6-1 Themes generated from semi structured interviews using reflexive thematic analysis

6.4.1 Engagement of participants

This theme provides contextual information. The study showed that not all participants engaged fully in the intervention. Despite 31 participants being recruited, only 19 of those completed full study measures and chose to trial the finger food menu over two lunchtime meals. It was important to understand the reasons why some participants did not engage fully and therefore a group of these participants were purposefully selected to be interviewed.

Participants who declined to trial the finger foods suggested the reason they did not choose from the finger food menu was because it was only offered at lunchtime. Some participants described that this was typically a time when they would consume a hot main meal. They suggested that they would prefer to be offered finger foods for supper, when they would normally have a 'lighter meal' or as a snack to be consumed between meals. Two participants explained the following:

> *"I prefer to have a main meal at lunchtime and a lighter meal in the evening. Which is typically a sandwich of some sort." (Participant 006 - Patient)*

> *"Definitely a lunchtime thing, rather than a meal in the evening... Umm yes it's more of a snacky food than it is a meal." (Participant 095 - Patient)*

One participant who declined to trial the finger foods felt that if the food were offered during the summer months they would have considered trialling them at lunchtime.

> *"Yeah exactly, and when its summertime and you can have lots of different foods and that's finger stuff… I have a sandwich at dinner… Because I find it easier. And I don't like being too full when I go to bed. I hate it. I can't bear being too full. But lunchtime I don't mind." (Participant 056 - Patient)*

It appeared that timing of when the food was offered impacted on whether participants chose to engage with the intervention. Limiting the trial of the intervention across one time of the day for this study, impacted on the uptake. Flexibility in timings of food to be offered appears to be important for participants to fit in with home eating habits. Home eating habits and familiarity of food played a larger role across participants' experiences.

6.4.2 Familiarity and food habits

Participants described how they attempted to continue eating habits from home in hospital. Staff interviewed described how many patients aimed to replicate their 'home routine' around mealtimes and eating behaviours and enjoyed having 'familiar foods'. One participant described selecting food items from the menu that they were familiar with and choosing to have the same meals repetitively, rather than trialling something new as displayed in the following quote:

> *"What I did find, I mean I like plain food in any case, and if there is something I like, I don't mind having it day after day, I do this at home, sometimes. I do it in hospital." (Participant 057 - Patient)*

This influenced the participants choices during the intervention trial as the participant only trialled foods he was accustomed to. For some participants, finger foods were similar to foods eaten at home, which supported engagement. Some participants were familiar with eating with their hands and therefore, when offered finger food foods in hospital, the same approaches to eating applied. This is illustrated by the quote below:

> *"Well yes, I always have done for pizzas, I don't know why but I have always used my fingers for pizza… I have it, probably, once a week. Just a small one." (Participant 018 - Patient)*

Participants who were familiar with eating with their hands enjoyed and engaged well in the intervention as it replicated similar eating behaviours to those at home. The experience of eating with the hands was perceived differently for groups of participants based upon their personal belief systems.

6.4.2.1 **Personal belief systems and eating with hands**

Belief systems can impact on an individual's behaviour and are made up of an individual's values and experiences. Acceptability and experiences of using finger foods on the ward appeared to be influenced by personal beliefs surrounding the concept of eating with the hands. These perceptions and preferences were based on individuals' culture and determined whether they found using finger foods acceptable to eat. Participants reported how acceptability of eating with the hands was impacted both by values learnt when growing up and generational changes.

Staff acknowledged that cultural background could influence perceptions of eating with the hands. Staff growing up in the western world described how they were raised to use cutlery and may have pre-conceived ideas regarding how patients should access meals. This is illustrated by one participant who stated:

> *"Certain cultures do eat with just their hands… I think we have in our head that we have to use a knife and fork and we have to use it in this hand… but what's more important… someone's health and independence or using cutlery."*
> *(Participant 072 - Occupational Therapist)*

A group of participants who were staff discussed how eating with hands could be associated with a 'childish behaviour' and therefore not appropriate for adults. As one participant stated:

> *"Generally, they're like quite… I don't want to say childish cos that sounds rude, but umm they are the kind of things that I would expect to see on the kids' menu" (Participant 100 - Student Nurse)*

Cultural backgrounds were described as influencing perceptions of eating. One dietitian acknowledged that expectations from relatives for patients to conform with familial traditions existed, despite patients having deficits that made eating with cutlery a challenge:

> *"Because we've all grown up using knives and forks and especially, relatives try and get their relatives or the patient to kind of be of… do the thing that they could do before, without always recognising that actually its far more difficult now." (Participant 086 - Dietitian)*

Another participant also acknowledged the changing culture of eating with the hands acknowledging that the 'fast food' culture for the younger generation was becoming more accepted and therefore a recognised need for hospital food to be offering this type of food. This is shown by the following quote:

> *"People do much more of a culture of you don't sit down with a knife and fork and have a napkin and everything now, it's much more what's accessible, fast food and eating out and about and things. I think that's become much more accepted." (Participant 086 - Dietitian)*

Generational views were a commonly occurring theme. Finger food was seen by some staff as 'modern' food and therefore better suited and accepted to patients of a younger generation. Generalisations were made by staff regarding patients' choices, expecting that most older patients chose more traditional English meals, however some were surprised that some of these patients also enjoyed the more modern finger food during the trial.

> *"I was surprised to see the pizza on the menu to be fair because I was like, 'Hmm, that's quite an unusual one to sort of offer older people' but it turns out some of them do like it." (Participant 024 - Ward host)*

Despite this study offering finger foods to participants aged 65 years or older only, the influence of generational views requires further discussion and thought to support future intervention development.

The context of eating with the hands was also raised by participants who were patients. Participants who were patients described looking to staff for reassurance with eating and to confirm whether it is appropriate for them to eat with their fingers. One participant questioned whether it was normal 'protocol' to be able to eat with your fingers, not wanting to disobey social etiquette. This is illustrated in the quote below:

> *"As long as you know you can use your fingers. You don't want to pick it up and eat it with your hands, well you wouldn't do that in a restaurant would ya?" (Participant 091 - Patient)*

Experiences of eating with the hands were influenced by the belief systems of patients, relatives and staff who were supporting the mealtime. Patient participants trialling the menu looked for staff acknowledgement to eat with the hands and staff had pre-conceived ideas based on their own values and experiences. It is also possible that relatives have their own views regarding etiquette and may want these to be followed.

6.4.3 Support from staff and visitors

Support from staff and visitors was an important theme generated from interviews and experienced in various ways for participants.

6.4.3.1 Reliance on a friend or relative at mealtimes

Some participants considered it necessary to have a family member present over mealtimes and described a sense of uncertainty if family members were not able to attend. Participants who had consistent support provided by families over mealtimes reported that if they were being supported well, they did not have a need for finger food. For example, one participant stated:

> *"I am lucky, so I have got someone to help me all of the time…. If he wasn't here I would be panicking a bit. It's nice to have someone… a presence of somebody that is a friend or relative especially at mealtime… as long as you have got that help and the normal food is fine." (Participant 095 - Patient)*

Other participants who were patients ensured that a routine had been set up to ensure family were visiting over mealtimes to provide support. One participant who was a patient described waiting for family members to be present rather than asking for support from staff:

> *"If I'm due a meal, I try and get my wife or daughter up here to help me…. Yeah I get them in to come about half past twelve, when dinner's here. So, they can help me… I just wait for them or sit and pick if I can." (Participant 084 - Patient)*

The same participant described reliance upon family to bring in food to replace hospital meals. Relatives bought in foods which were easy to eat and interestingly could fit the definition of 'finger food'. For this one participant these foods were considered necessary and replacement for what the hospital was providing:

> *"My wife and daughter have been making me pastas, quiche, little finger sandwiches, I think I've still got tomatoes there." (Participant 084 - Patient)*

For others, when family and friends bought in foods, these were seen as treats to supplement the hospital food that had been provided.

> *"Mind you, I did have a little bit of luxury. (Wife) bought in strawberries and raspberries… well yeah… Some people say what? Why you bother doing that. Because it added a lovely, tasty flavour." (Participant 077 - Patient)*

A minority of participants relied upon family member and visitor support over mealtimes and had consistent mealtime support they relied upon every mealtime. For the majority of participants, support for meal preparation and set up was provided by members of staff.

6.4.3.2 **Help from staff**

Participants described how staff support was requested to open packaging, which would have taken the patient time and effort to open independently. This related to the standard meals and finger food meals, meaning that similar support for finger food meals was required. One participant stated:

> *"Sometimes the sandwiches are wrapped up, and the nurses open it up for me… sometimes the wrapping isn't easy for us to open… Bit tricky. But normally there is somebody to help us. So, there's not… it can easily be overcome. But I find the biscuits also are not easy to open up." (Participant 080 - Patient)*

Patient participants interviewed also described receiving support from staff members with cutting food. Adverbs such as 'normally' and 'sometimes' were used when describing the support received by staff supporting the notion that it is not always readily available. Staff support was either provided when they noticed a patient struggling, or when patients who required support 'asked nurses' for help.

> *"Sometimes if they can see I can't open something, or I can't cut it, they will come across and ask me if I want some help. And I do ask the nurses as well… Cos it is a great help if you can't cut the food. Particularly if its meat… chicken or pork or beef." (Participant 080 - Patient)*

Some participants interviewed did not recognise the support they required to eat or did not want to admit to needing support and asking for help. One participant explained:

> *"No, I hadn't needed any help. Although today the nurse came up and I asked, 'Could you cut through this sausage roll?" (Participant 003 - Patient)*

One staff member commented that finger foods could support the rehabilitation process, as often when staff see that patients are unable to eat independently, help is provided by simply 'doing it for them' rather than supporting their independence and rehabilitation. This is illustrated in the quote below:

> *"We are quite guilty for just taking over and doing it for them. Because they can't use both hands, we're not going to hand them a knife and go, "There you go, have fun trying to cut it," sort of thing…I think finger foods a good idea because sometimes, especially in stroke, it prompts them to use that other hand as well… it sort of works in the rehab side of things" (Participant 026 - Health care assistant)*

Despite being given finger foods designed to enable independence across mealtimes, participants who were patients continued to be reliant upon friends or relatives to provide mealtime support and to bring in additional food items. Help from staff continued to be imperative on the ward during the finger food intervention trial, to support with food preparation such as opening packaging and preparing food to be eaten.

6.4.4 Visual appeal

The visual appeal of finger foods influenced acceptability. The properties or physical attributes of finger foods were described as the 'visual appeal' and included 'texture, temperature and taste'. The properties of the food impacted on the practical abilities of using them on the ward. The majority of participants interviewed indicated that they found finger foods easier to manage, as they were presented in a manner that could be easily accessed. However, for some, challenges in practice were recognised.

Participants commented positively upon how finger foods looked upon serving. Participants who were patients appreciated the care taken to ensure good visual appeal and staff remarked on how presenting the food was important to support the patient's recognition of food.

> *"It was served up nicely. Not just slap, bang job done." (Participant 003 - Patient)*

> *"I think it looks quite good. Sometimes I think it looks better than like your lasagne slopped on a plate and that and it's all fallen apart." Participant 026 -*

Within visual appeal, the texture, temperature and taste of food was equally important for those participants who trialled the intervention.

6.4.4.1 **Texture, temperature and taste**

The finger food menu for this study was developed to be suitable for patients able to manage a level 7 regular diet (IDDSI Committee 2016). The international descriptors describe foods suitable for a level 7 diet as everyday foods including a variety of textures and no texture restrictions (IDDSI Committee 2016). They were therefore *not* suitable for patients recommended a texture modified diet secondary to oro-pharyngeal dysphagia.

Although all participants included in the study were assessed to be able to manage a regular diet, some described still being concerned about swallowing difficulties and were looking for items on the menu that were softer or easier to chew. Older adults also showed a preference for food to be easy to chew.

> *"Yeah. The carrots are done properly, they're not al dente, I like them nice and soft." (Participant 084 -Patient)*
>
> *"Yeah I think when you are older, you don't want too much chewy food" (Participant 037 - Patient)*

Temperature of the food was felt to be an important consideration to patient's acceptability and enjoyment of the food. Perception of the temperature of the food was based on what food the participant ordered. Positive description of food temperature was provided when hot food was served.

> *"I don't know… it was hot, it was lovely. It was like the deep crust one. The topping was lovely. Really moist, really tomatoey and cheesy." (Participant 095 - Patient)*

Some patient participants described that food was cold by the time they received it, which impacted on the texture. Participants described how the meal delivery method impacted on the food temperature, with patients being served last receiving colder food. Reduced temperature food was acknowledged by staff. 'Cold chips' continued to present as a problem reported by staff.

> *"I know sometimes, with the cooked meals, I find the time they seem to get round to me, they are a bit on the chilled side. And a bit chewy. OK, depends what it is of course." (Participant 037 - Patient)*

Patients not being prepared for meals to be served was also a factor impacting on the temperature of the food. For example, patients who go to the toilet or are sleeping as the food is served, then come back to a cold plate. This is illustrated by the quote below from a ward host.

> *"When they were saying they were cold like maybe they didn't eat it straight away or they might have, when it's delivered they might be asleep, cos you've just got to wake them up cos they might have just nodded back off again." (Participant 024 - Ward Host)*

Considerations to the texture and temperature of food is discussed as an important factor. Considering the intervention was trialled with participants aged 65 years or older, understanding whether 'softer' food items for younger stroke survivors is important will need further investigation prior to future trials and menu developments. The texture and shape of the finger food provided also impacted on the ability to eat.

6.4.4.2 **Finger foods are easier to manage**

For some participants, eating finger foods was described as easier to manage as there was 'nothing to worry about'. Participants indicated this was particularly useful where recognition and of cutlery was a challenge for those with cognitive or physical deficits as a result of the stroke. This is illustrated in the quotes below:

> *"I really, really liked the pizza, and that was so simple. Cos it didn't come with anything that I had to worry about." (Participant 095 – Patient)*
>
> *"I think they are a good idea for everyone. Especially sort of within stroke and stuff like that if they are on the normal diet because their cognition does get affected quite a lot by the stroke having something that they can just pick up. They don't have to worry about associating the knives and forks." (Participant 026 - Health Care Assistant)*

Participants who were patients described the importance of having finger food that was easy to eat and presented in a way that could be eaten without making a mess.

Participants reported avoiding foods that made a mess when eating and, choosing foods that were easier to manage. One patient participant admitted to avoiding items on the standard menu which would be difficult to eat with cutlery. This was echoed by staff participants who acknowledged that patients can be concerned about how they were going to manage the meals that they had ordered and were not necessarily directed towards something 'easy to eat' at time of ordering.

> *"If I'm sort of sitting down on the chair with the table in front of me, then it doesn't make a lot of difference… But yes, I'll probably avoid something that*

> *looks overly messy in terms of where I'm likely, have bits that are going to fall off the spoon or fork or something." (Participant 006 - Patient)*

> *"I think a lot of them worry about whether they're, how they're going to eat it and stuff like that. a lot of them do go for the hot meals that aren't finger foods and then go, 'Oh wait, I've got to cut that bit of chicken'" (Participant 026 - Health Care Assistant)*

Having food that did not cause additional mess to eat was important to participants who displayed conscious thoughts regarding the public setting of the hospital and potential for people to be looking at them whilst eating with their hands.

> *"I mean …The fish could have been picked up easily with your fingers… but the bananas and fruit… no… Because of the risk that they might slip out." (Participant 077 - Patient)*

Some participants said that some of the food items provided were not appropriate to eat with the hands due to the way they were presented or cooked. Vegetables that were over cooked were deemed impossible to pick up with hands.

> *"In other ways, the fish wasn't fish fingers; it was fish in a chunk, which was a bit beyond picking up, with the fingers… And there again, picking up broccoli, if its finger food, can't really pick up broccoli, particularly in that state, just mush." (Participant 055 – Patient)*

One participant interviewed described the idea of finger foods as 'very good' to avoid the physical difficulties with using cutlery. However, in practice there were flaws with the intervention, meaning it wasn't practical to use.

> *"Umm… the idea in theory is very, very good, especially when I first thought about, cos I thought great that means I don't have to try and struggle with a fork or a knife, but in practice, I don't know that it is really practical. Which will probably be a bit of a shame for a lot of people." (Participant 095 - Patient)*

This participant went on to discuss the difficulties found accessing and opening packaging and sauces, which impacted on the ability to access these foods independently.

> *"If you can pick it up with your fingers that's fine, but you still need to open the wipe and if you have only got that one hand it's really difficult. And that goes the same with the vinegar and ketchup or any accompaniments. The cheese was impossible to open, even for an able-bodied person." (Participant 095 - Patient)*

One challenge acknowledged by patients and staff interviewed was the hand hygiene. Participants who were patients discussed the importance of being able to wash hands prior to eating and were wary of infection spread by lack of hand hygiene.

> *"Uhh some bits I would be happy with my fingers… umm I'd always get a wipe for my hands whatever food I'm having, cos they can get mucky, and we all know they carry infection… I don't like these sort of instant pump gels I like to get hold of a little bar of soap 'til the surface covers my hand and goes white." (Participant 077 - Patient)*

Others described how preparation of hand washing was impossible to conduct independently. If they were provided with a hand wipe this caused additional difficulties to either open the packet or leaving a taste on the lips. Generally, participants who were patients did not comment on the role of staff to support with handwashing.

> *"I didn't know what to do with them apart from with the wipe. And the wipe leaves a bit of a taste in your mouth, if you then touch your lips…" (Participant 095 - Patient)*

Cleanliness was seen as a top priority for staff interviewed, prior to eating finger foods. Some members of staff interviewed, including therapists, who were not always present at mealtimes on the ward, assumed that all patients washed their hands prior to eating. Other staff members, such as nursing staff and health care assistants, acknowledged that cleaning patients' hands was a task that doesn't happen on a regular basis, was not prioritised and sometimes just forgotten. Where washing hands prior to a meal was prioritised, there were no concerns, however it was a task that nursing staff felt they need to be doing more regularly.

> *"Yeah well I guess about cleanliness is a big thing… but assuming everyone should have their hands washed before a meal… I don't think there is anything wrong with that." (Participant 072 - Occupational Therapist)*

> *"We just need to get better at hand hygiene with our patients. I mean we forget. Like they give out these but no one I have never in my whole year of being here ever seen a patient pick up and use it.. if we are going to promote finger eating is to remember to clean our patient's hands before." (Participant 067 - Staff Nurse)*

6.4.4.3 **'Energy dense, small packets of food'**

This theme encapsulated the impact of portion size and nutritional value of the finger food, where smaller portions of higher energy food were seen as advantageous. Participants described how portion sizes impacted on their desire to eat. Finger foods were perceived as smaller portions, which was described as a benefit to people with small appetites. Finger food seen as a 'light' option was described by both staff and patients interviewed:

> *"Very nice indeed. It was umm it was not too much. And it was enough to fill you up…. I enjoyed it.." (Participant 057 - Patient)*

> *"Side Room 1, she quite enjoys her finger foods. You always see the patient like that always chooses a sandwich because it's easy for them to eat and like I said*

> *older people, their appetite's not great anyway, is it, so they do choose a sandwich because it's light." (Participant 026 - Health Care Assistant)*

Some patients interviewed described how the hospital environment impacted on their appetite and what they wanted to eat. This included what else had occurred during the day and which stage of recovery they were at. For these participants, finger foods were accepted as a lighter option that fitted in more flexibly with ward patterns. As one participant indicated:

> *"Sometimes you don't always feel like a full meal. Particularly if you've been and had tests prior to having dinner, you don't always feel up to scratch to eat a lot… it's a nice way of not having to eat too much" (Participant 080 - Patient)*

Participants interviewed had varied insights into the nutritional value of the food. When asked about the nutritional value of the finger food, most patient participants suggested nutrition was not a priority and not something they were concerned about, however felt that finger foods would be a less healthy option.

> *"I have no idea; they are probably not half as healthy as some of the other things… But then after a while you think, well does it really matter, I am just sat here anyway." (Participant 095 - Patient)*
>
> *"They all look like quite tasty greasy spoon foods, which isn't necessarily a bad thing." (Participant 100 - Student Nurse)*

Participants who were staff described how good nutrition related to the range and variety of food items offered. Staff interviewed described a plate including protein, carbohydrate and essential nutrients as good nutrition. Staff participants felt that patients did not consider the nutritional value of food they were ordering and ate what they wanted in hospital. Despite the finger food being served as smaller portions, staff identified that providing an increase of energy could make a big impact on the overall dietary intake of patients.

> *"We're thinking calories and energy, they're thinking, whatever I feel like I'd like tasting. And actually, sometimes that is a struggle with that, so we've got patients who you know, it's trying to get them to eat more things but actually I just don't have the energy, I'm tired, I can't fit it in. So actually, some of these nice energy dense small pockets of finger foods make a big difference." (Participant 086 - Dietitian)*

For other staff participants, providing fruit in a different format (as finger foods) was seen as a more nutritional option compared to the other desserts on the standard menu. Fruit presented as finger food provided patients with the opportunity of accessing these types of food, which are typically hard to open and prepare independently. One participant said:

> *"It is nice to see them actually getting offered the fruit as part of the finger foods because a lot of them will go for a cheesecake or a trifle and the ice cream and stuff like that. They at least if they've got that opportunity to eat a*

> *little bit better like the chopped-up banana and the oranges and stuff like that." (Participant 026 - Health Care Assistant)*

Overall, finger foods were seen as 'lighter' meal option presented in smaller portion sizes. This often fitted in with participants' desire to eat, which was typically impacted by the acute ward environment. Despite being a smaller portion, finger foods were described as 'energy dense' by members of staff. Members of staff viewed nutrition as a higher priority than patients who were interviewed. In addition, staff who were interviewed showed more concern regarding the safety and sustainability of using a new menu within the ward context.

6.4.5 Acceptability within the ward context (impact of context and environment)

6.4.5.1 Safety aspects

It is important to consider any 'fatal flaws' in the feasibility trial, that may require refining prior to a main study (O'Cathain et al. 2015). Participants were asked about any safety concerns with using the finger foods that occurred during the study. There were no perceived safety concerns within the trial, however staff commented on potential safety concerns for future. Hand hygiene and washing hands prior to eating finger foods was valued by participants; however, this was not commonly supported on the ward. Participants who were patients described not being provided with the opportunity to wash their hands prior to eating and participants who were staff described guilt due to not having the time to support handwashing. Risk of choking on the finger foods was acknowledged by staff interviewed, however not always a concern for patients interviewed and did not occur during the study.

Choking risk was recognised as a hypothetical safety element to consider with the use of finger foods. Staff suggested that the risk of choking would not necessarily be down to the food provided but more the individual patient's feeding technique. Finger foods were described as having the potential to reduce choking risk, as patients would have more control over the pace of feeding and have sensory awareness to be able to prepare themselves for eating. As one participant stated:

> *"Well, in some ways finger foods might actually be a bit safer because they are already cut up into bite size pieces… but if someone thinks oh well its bite size, I'm just going to shove it all in, then that could be problematic from a choking point of view, so they would always need, someone needs to keep an eye on them." (Participant 093 - Speech and Language Therapist)*

The fact that staff are still required to 'look' out for patients or 'keep an eye' suggests the requirement for ongoing staff support.

> *"With the satsumas, there might be seeds or pips in them, so we'd have to look out for that I'd think, because they could choke. Even if they are on normal foods, a seed, like you wouldn't be expecting it, so they might it might make them choke. So, that would be something to look out for." (Participant 066 - Health Care Assistant)*

Texture of the food was reported as important, particularly for patients with dentures who may find hard food more difficult to manage. Staff interviewed were very aware that finger foods were not appropriate for patients on modified textured foods such as puréed diets. They acknowledged that food options could be provided that are 'easy to chew' and appropriate for older people who may have loose dentures or find hard chewy food more difficult to eat. One participant stated:

> *"Chewing, they might get bored of chewing if it's quite tough, or if they have dentures." (Participant 067 - Staff Nurse)*

Staff interviewed described how the temperature of the food would need to be monitored, particularly for patients with cognitive deficits who would not necessary be aware of monitoring these sensory actions themselves. This was spoken of hypothetically and illustrated by the following:

> *"Cheese can go molten as it were… with it being toasted. So obviously that, we'd have to be careful with that… with patients because they may not if they are cognitive… they may not think about that. They may just see a sandwich, bite into it and have… very burnt mouths." (Participant 093 - Speech and Language Therapist)*

> *"If you are looking at finger food as some sort of snack as they're ready… the food going cold would probably be the main one… or could they have some biscuits here, just a couple of dried foods out throughout the day." (Participant 072 - Occupational Therapist)*

No safety concerns were observed during the trial, however staff raised important safety topics which would need to be monitored in a future trial including risk of choking and temperature of food.

6.4.5.2 Making change in a complex system

Staff acknowledged the complexities of hospital mealtimes and challenges with adopting a flexible approach to finger foods in the current regimented timescales for hospital meal provision.

At ward level, the ward host described the ordering procedure as 'not as complicated as it seems once you know the procedure', suggesting that time and training is key in making the system work.

> *"You've just got to remember when you're in your tablet you got to go out of the bit that you're already in for the multi portion and the purées, you've got to*

> *go out of that and go into another bit to find it all and then select the patient to send it… it seems more complicated than it is but if you know, if you knew, then it's different." (Participant 024 - Ward Host)*

However, complexity of tasks increased as some foods served on the finger food menu required alternative cooking times, adding increased demands to the ward host's job.

> *"The only one that is a pain is the pizza, because that one doesn't go on the full 65-minute cycle. You've got to remember to put it in I think 20 or 25 minutes before the end of your cycle." (Participant 024 - Ward Host)*

A dietitian interviewed suggested that implementing the finger food menu added additional layers of complications to an already complex process.

> *"Well adding an extra one (menu) is adding an extra layer of complications." (Participant 023 - Dietitian)*

The dietitian described how some staff members have 'hang ups' or ideas about appropriate behaviours or choices at mealtimes which do not put the patients' nutritional care at the centre. In the example below, the dietitian acknowledged that a patient's priorities may change during their hospital stay and staff may disagree about the best support required.

> *"Some have hang-ups about what goes together and what doesn't go together, what's an appropriate thing to eat in certain situations and what isn't. And umm so I think it probably just highlights the fact that, it's the nutrition that's important. We all have different ideas about how you get that for different people... But in many cases... our priorities change if we have limitations which I guess is what this study is about." (Participant 086 - Dietitian)*

Indeed, finger foods were seen as something new and not 'traditionally' used, meaning integrating them into every day practice would be more of a challenge.

> *"The things I see before are things any patient, well not any patient but any patient on the normal diet could be offered. But don't traditionally I suppose." (Participant 023 - Dietitian)*

The need to serve food flexibly also challenged the appropriateness for change in a hospital setting. The 'regimented' mealtimes were reported by staff, suggesting that food availability is compacted to certain times of the day, and using finger foods could support more flexible dining.

> *"Very regimented mealtimes in hospital and erm it's not like you can just pop down to the kitchen when you are a stroke patient and you know get yourself an afternoon snack, because you were like, you weren't hungry and lunch so yeah, things like that can be better and last a bit longer I'd imagine." (Participant 100 - Student Nurse)*

Considerations to using finger foods in a ward context and making change was important from participants who were staff. Making change within the regimented structure of a hospital mealtime was described as adding extra complications and going against tradition.

6.5 Chapter conclusion

Chapter six presented qualitative interview data from participants who were patients and members of staff involved in the intervention to support understanding of the acceptability of using finger foods on the stroke rehabilitation ward. Participants were purposefully sampled to gain a range of viewpoints and to explain the quantitative results presented in Chapter 5. Initially, reasons for varied engagement with the intervention were explored, which appeared to relate to the timings employed in the study design.

Acceptability with regards to food choices is a multifaceted domain aligned with varied viewpoints and preferences of food choices and cultural influences. The importance of patient-centred nutritional care, considering patients' familiarity with finger foods and home food habits with the complexities of the intervention delivery, highlights the importance of conducting intervention studies within the 'real world' context.

The next chapter will integrate the qualitative interview findings with quantitative data presented in Chapter 5, discussing key recommendations for a future study.

Chapter 7 **Mixed methods discussion**

7.1 Introduction

This thesis has explored the feasibility and acceptability of using a finger food menu, on a stroke rehabilitation ward in England, using a mixed methods approach. Based on the MRC complex intervention guidance (Craig et al. 2008), this thesis presented the ‘intervention development’ stage and a feasibility study to establish whether a larger study could be delivered (Williams 2016). This systematic approach is recommended by the MRC prior to the full evaluation of a complex intervention (Craig et al. 2008).

As part of the feasibility study, many issues identified from previous literature were addressed (Heelan et al. 2019). For example, the integrative review by Heelan et al. (2019) showed that published studies evaluating the use of finger foods had documented limited detail regarding the data collection methods and intervention development and were addressing research questions that would benefit from both quantitative and qualitative data collection. Therefore, those studies provided insufficient evidence in terms of robust outcomes and details of the intervention to fully satisfy whether the intervention was effective. In addition, there was a paucity of research addressing the use of finger foods in hospital settings and a lack of consideration to implementation strategies and implementation science principles.

This feasibility study showed people with acute stroke in hospital were willing to take part in the study. Expected recruitment rates were met, but a high attrition rate was the main issue of concern. A reliable method of data collection produced promising clinical outcomes, which showed that an adequately powered Randomised Control Trial (RCT) has a good chance of demonstrating clinical and health-economic effectiveness. Importantly, the intervention was considered acceptable to most participants and strategies to support the scale-up of the intervention relating to the context, facilitation and innovation described. The qualitative data provided additional information, from a proportion of participants, which will be used to understand the quantitative findings in more depth.

The main advantage to mixed methods research is the intersection of both the quantitative and qualitative data collection strands. This integration provides further insight into results and valuable interpretation of the data to answer the research questions (Creswell and Plano Clark 2018). This chapter presents a discussion of the findings from both quantitative and qualitative data, which are integrated to answer the feasibility research aim and objectives (Creswell and Plano Clark 2018) and make recommendations for a future trial. Key findings are explored considering the relevance of the results in the contexts of other published literature (Eldridge et al. 2016a).

This chapter is divided into two key sections. These are:

- Methods of mixed methods analysis.
- Key discussion points from the mixed methods results.

The following chapter (Chapter 8) provides a summary of the research findings including recommendations for future research, a reflection on the PhD candidate's clinical academic role and consideration for future publications.

7.2 Methods of mixed methods analysis

There are specific approaches to integrating data in mixed methods research depending on the design of the study (Fetters et al. 2013). For this feasibility study, qualitative data were used to provide a strong explanation of the quantitative findings. Quantitative and qualitative data were analysed separately; the results were interpreted descriptively (Creswell and Plano Clark 2018) and presented separately in Chapter 5 and Chapter 6. Findings from quantitative data that were unexpected or unusual were isolated and then qualitative analysis used to further explore and explain results. Common concepts were identified and presented within a joint display (Creswell and Plano Clark 2018). Consistencies and discrepancies were addressed within the data sets and the interpretation of the results based on the joint display.

7.2.1 Validity in mixed methods analysis

Creswell and Plano Clark (2018) provide general overarching principles of validity for mixed methods analysis. Firstly, Creswell and Plano Clark (2018) highlight the importance of validity checks associated with both quantitative and qualitative strands. For this feasibility study this is reported in section 4.11, page 132. Therefore, the merit of each strand is accounted for within the discussion below. Secondly, because Creswell and Plano Clark (2018) describe that threats to validity vary across designs, strategies for addressing such threats are viewed in terms of mixed methods design.

For this sequential design, the collection of quantitative data was followed by the collection of qualitative data. To minimise threats to validity the following strategies were used:

- All quantitative results were considered for explanation, including significant and non-significant results. This limited the threat of failing to identify all important quantitative results.
- Qualitative data collection was designed to further investigate surprising results to avoid threat of not explaining surprising results
- The qualitative sample was purposefully selected to avoid the threat that quantitative results do not align with qualitative results.

The discussion points below are based upon the assumption that results from both strands of this programme are equally weighted. This is the most likely threat to the legitimacy of these results. Therefore, the discussions that follow include consideration of the relative merit of each strand with particular emphasis on the relevance and accuracy of the questions asked and/concepts measured.

Key discussion points focus on the recruitment process, outcomes and measures, intervention content and delivery, and informing a future trial.

7.3 The recruitment processes

Thirty-one participants were recruited within an eight-month period meeting the criteria pre-specified to support recruitment to a future trial. Generally, findings from this study suggest that recruitment to a future larger study is possible and there is a sizable patient population willing to take part. However, recruitment is known to be the biggest barrier to any study (Treweek et al. 2013) and challenges in recruiting people after stroke have been documented over the past two decades (Feldman et al. 2017). To enhance successful recruitment design in a much larger study, findings from this feasibility study can be used to understand the reasons behind success (Hubbard et al. 2015). This will avoid the risk of a future underpowered study which is likely to take longer than anticipated, be resource intensive and inconclusive (Treweek et al. 2018).

There are several recruitment processing issues that merit further discussion prior to recommendations being made for future recruitment strategies.

7.3.1 Recruiting and retaining the study sample

7.3.1.1 Representing the study population

It is important that the study sample represents the population to allow for generalisability of results. People after stroke were chosen as a population who had high risk of reduced oral intake, eating difficulties and a under researched group for providing support for oral dietary intake.

The researcher recorded data about age, gender, and stroke severity to understand the diversity of participants recruited for the study. Demographic data on the race or the ethnicity of participants in the study was not collected, therefore remains unknown. The finger food menu for this study was based upon the standard hospital menus provided in the Trust, which catered mainly to a western diet. This could have impacted the population attracted to take part in the study and limit the ability to generalise findings at a population level.

In a future study, it would be of interest to understand the experience of a diverse population on using finger foods as a person's background can influence mealtime rituals, meal choices, acceptance of support, and eating position. A future study should further consider ways to encourage diverse participation and to understand the views of a diverse patient group. Accessing patients and public representatives from a wide range of backgrounds would support the development of recruitment strategies for a more diverse group.

The population for this study was also limited by the strict eligibility criteria. These criteria were chosen as the intervention was only able to appraise people eating ‘regular textured’ foods. People over 65 were chosen as a group representative of ‘older adults’ on the stroke ward. The median age of stroke in the UK is between 74-80 years of age (Royal College of Physicians Sentinel Stroke National Audit Programme (SSNAP) 2020). However, only 45% (n=84) of patients screened for the study were eligible, with (n=58) not eligible due to having a textured modified diet. Twelve percent (22 of 185) of participants screened for the study were ineligible due to being under 65 years old. High rates of ineligibility raise the question as to whether the population targeted was most appropriate.

Textured modified diets are commonly used in clinical practice for people after stroke and determined as one of the most evaluated interventions to reduce the rates of pneumonia in patients with dysphagia (Foley et al. 2008). Therefore, it was unsurprising that many patients on the study ward were recommended textured modified diets and were not eligible to participate in the research project. Studies included in a systematic review of randomised control trials by Foley et al. (2008) showed textured modified diets were frequently recommended during the first few weeks following stroke. This is because early detection and treatment of dysphagia is associated with reduction in morbidity, mortality and length of hospitalisation (Hinchey et al. 2005). The sample used for this study had a mean length of hospital stay of 16 days (range 3-59 days) and therefore were within early days of rehabilitation and likely to be treated for dysphagia.

For this study, those excluded due to being on textured modified diets were those patients who had been recommended any diet not considered a ‘level 7 (regular)’ diet on the International Dysphagia Diet Standard Initiative (IDDSI Committee 2016). Similar patient groups were recruited to a study by Bailey (2007) which evaluated the use of finger foods for patients in intensive care. Bailey (2007) similarly included only patients able to manage a regular textured diet and therefore reported high rates of attrition, considering that once regular feeding approaches were established that patients were typically discharged from the ward.

This feasibility study focused on providing finger foods to those aged 65 years and over; however, in qualitative interviews staff suggested that finger foods would be more acceptable to the 'younger generation' of patients, who were not included in this study. Staff reported that these younger patients have grown up with a 'fast food' culture and are used to eating the types of food provided as finger food. Some staff members acknowledged a shift in food preferences and ways of eating amongst generations and described the finger food provided such as pizza as more 'modern' food.

Understanding the population for which a menu has been designed has been reported elsewhere in the literature to improve acceptability with the knowledge that food preferences have the potential to change across the lifecycle (Spangler and Pettit 2003). A survey study conducted in an Australian teaching hospital showed that views on food preferences have altered over the 12 years, with preferences of patients in the 2000's leaning towards the more traditionally gourmet foods, which are from various cultures and with high nutritional value (Kennewell and Kokkinakos 2001). The study supported previous claims that age demographics were an important aspect of menu planning, with preferences of the older inpatient population significantly differing from those of a younger inpatient population (Kennewell and Kokkinakos 2001).

This provides important information regarding who should be considered in future research. Not enabling patients under 65 years old to participate narrowed the eligibility criteria and therefore limited those who could take part in the study. Despite under 65s being a minority within the stroke population they continue to experience eating difficulties (Klinke et al. 2013) and restrictions in mealtime participation.

The population available for a future trial of finger foods suitable for patients on a level 7 'regular diet' should be considered. Future research should consider relaxation of the eligibility criteria to provide finger food options to patients on textured modified diets, considering that overly strict eligibility criteria can impact the recruitment efficiency of trials (Elkins et al. 2006). This has been previously explored by Nangeroni and Pierce (1985); Barratt et al. (2001); Pouyet et al. (2014) highlighted in Chapter Two, who trialled using softer foods and puréed forms (Pouyet et al. 2014) of finger food for older adults who may have difficulties chewing or dysphagia. However, acceptability of textured modified finger food was not fully evaluated for people in hospital in the

UK and examples of foods appropriate for these diet types were not fully reported. A future study should also consider finger food which is appropriate across generations.

7.3.1.2 Overcoming challenges with the consent process

Twenty-six participants (84%) were able to consent to the study by making a valid and informed decision stating that they wanted to take part. This was despite 94% of the sample having cognitive impairment which could have impacted on their ability to consent to the study. Many studies choose to exclude people with cognitive or communication difficulties based on the difficulties of obtaining ethical consent, however in this population it can be deemed more unethical to exclude them as this would invalidate the sample (Shepherd 2016).

As a registered SLT, the PhD candidate had prior knowledge and skills for supporting patients after stroke to communicate. SLTs are recommended to be involved in capacity assessments for people with brain injury to support informed decision making (Office of the Public Guardian 2007). The researcher provided visual aids and adapted communication and patient information sheets to promote participants to be involved in decision making, according to the participants' needs. This provided the opportunity for patients with communication needs to take part in research.

The PhD candidate's professional background supported decision making in this study; however, other studies show that SLTs' role in supporting people with aphasia to make decisions according to the Mental Capacity Act is not well understood or highly valued (Borrett and Gould 2020) and often SLTs in England are not consulted to support decision making (McCormick et al. 2017). Future trials, including people after stroke, should incorporate support from an SLT to enhance patient decision making and involvement in research.

One challenge to the consent process was the written consent required from participants. For many patients, their dominant hand had been affected by the stroke, making it difficult for them to sign the form. For some participants, signing the consent form and filling in information was the first time they had attempted to write since their stroke and caused their new deficit to be acknowledged. For some this was quite an emotional time.

Future studies should consider the need and requirement for written consent and consider alternative ways in which consent could be documented depending on neurological impairment. Five participants required a personal consultee to support the decision-making process regarding taking part in research. For one participant, this was only to sign the form. Future research should include views of participants who may require support to provide valid informed consent through a personal consultee.

Timing for gaining consent was a limiting factor to recruitment. Adequate time to freely consider participation in research provided assurance that participation in the study was voluntary (Health Research Authority 2012). However, due to frequent bed moves and discharges in the acute environment there are pragmatic and ethical dilemmas. According to the study protocol, participants were required to have participant information sheets for at least 24 hours prior to the researcher returning to gain consent. Eight participants, who had received patient information sheets, were discharged from the study ward prior to the researcher returning to discuss the study further. The researcher couldn't eliminate unexpected discharge from the ward. In future research, the eligibility criteria should ensure that discharge is not anticipated for the duration of the data collection period.

7.3.1.3 **Impact of recruitment using a single, clinical academic researcher**

The PhD candidate was not available to approach 15 potentially eligible participants as outlined in the participant flow diagram in Figure 5-1 due to the recruitment process relying upon availability of the lone researcher. This meant that timing and availability for recruitment was limited. Increasing the number of recruiters to two or three is shown to increase recruitment rates (McGill et al. 2020b). However, the systematic review by McGill et al. (2020b), investigating features of randomised control trials with people after a stroke that were associated with efficient recruitment, also showed that recruitment rates were slower when researchers were responsible for recruiting to multiple sites compared to one recruiter per site (McGill et al. 2020b). This review included stroke survivors who were residents in community, hospital and rehabilitation beds and did not focus on rehabilitation efforts for eating and drinking. It does, however, reveal useful insight for a future multi-centre trial.

Having one researcher with previous clinical experience of working on this ward and motivated to recruit for the study supported recruitment. Attributes of the recruiter as key to successful study recruitment has been reported elsewhere. The analysis of qualitative interviews by McGill et al. (2020a), undertaken with stroke rehabilitation triallists, outlined the key attributes of a successful researcher. McGill et al. (2020a) describe the ability of the researcher to build and maintain a positive working relationship between team members as key to success. As the researcher was conducting this study alone and relied upon information provided by clinical staff, strong working relationships with the clinical team provided awareness of eligible patients.

It is important to consider that, within this study, the opportunity to recruit participants was limited to the three days per week allocated as research days within the PhD candidate's clinical academic role. This reduced the time available for approaching potential participants. Based upon this discussion, successful recruitment in a future, larger, multicentred trial would benefit from one researcher per site doing the recruiting. This person should have previous experience of working with the study population and existing good working relationships with staff prior to the study commencing. The researcher should also be flexible with timings for recruitment.

7.3.1 Predictions for future study sample

From this feasibility study, an estimation for a future sample size was made. It was estimated that 330 participants (165 in each arm of the trial) (see 5.9, page 178) would be required, based on energy intake as the primary outcome and upon using a similar population to this study. Energy intake was used as the primary outcome measure here, however, further discussion regarding the most appropriate outcome for a future study is presented in section 7.4.3, page 215.

In this study, finger foods were described as foods that were ‘easier to manage’ and therefore appropriate for patients with cognitive impairment. Not requiring associating a knife and fork for eating was seen as a benefit for patients with cognitive impairment and therefore does reveal that other patient groups presenting with these impairments may also benefit.

If participants in a future study were to include patients with different conditions such as dementia, as recommended by the literature cited in Chapter Two, then researchers would need to question whether they should consider altering their recruitment methods and criteria. Considering that the sample for this feasibility study had a high association with cognitive impairments, with 94% of participants recruited to the trial showing signs of cognitive impairments, this may mean that recruitment issues similar to those already discussed in this study will arise.

Whether similar results will be seen with a different sample population, such as people with dementia in hospital, is interesting. The eating difficulties in this study discussed for people after stroke are similar to those seen in people with dementia. However, the acute changes in stroke are not specifically seen in those with dementia who experience progressive decline in eating difficulties. For people with dementia, eating difficulties can be exacerbated by being in hospital which is not their typical environment. In addition, issues of acceptability may alter between the patient groups and it would be beneficial to establish these in a future study. The context of a future study will need to be considered to ensure that strategies are in place to support successful implementation. Strategies relating to context are further discussed in section 7.6.1.

7.4 Outcomes and measures

In general, the evidence from this feasibility study suggests that obtaining data to measure dietary intake as a primary outcome is possible. The provision of a finger food menu showed an encouraging trend towards increasing energy and protein intake. In line with CONSORT guidelines, the true effect of the intervention was not assessed in this feasibility study (Eldridge et al. 2016a). This small study was not designed to produce results of effect, and no significant results were found. Prior to making recommendations for a future study, considerations should be given to feasibility elements from this study, including the possible impact of missing data, study design and follow up time, statistical tests and the reliability and clinical significance of dietary intake results.

7.4.1 What contributed to rates of missing data?

Full outcome measures were only recorded for 61% of participants. The evidence of high levels of missing data needs further consideration to ensure that a future study does not encounter similar problems. Reasons for missing data were recorded in the participant flow diagram in Figure 5-1, page 141. They are further explored considering the qualitative findings in section 6.4.1, page 190.

High rates of attrition limited the amount of data collected and analysed quantitatively for the study. The stroke rehabilitation ward was pragmatically chosen as a subgroup of hospitalised patients who were likely to benefit from the intervention due to the participants' prolonged periods of admission and less frequent ward moves; however frequent discharges and ward moves during the study period remained a challenge.

High rates of attrition have been discussed in a pilot feasibility trial of a nutritional intervention by Collins et al. (2017b). Collins et al. (2017b) piloted a new menu higher in energy and protein and nourishing mid-meal service under standard foodservice and multidisciplinary care conditions in the subacute setting in a geriatric ward in Australia. Collins et al. (2017b) attempted to collect food intake data at admission, day 14 and day 28; however, described food intake data was not available at day 14 for 41.1% of participants due to natural attrition of the ward e.g., discharges or ward moves. Shortening the follow up time to three days was seen as a method of reducing the risk of attrition.

Future research should consider designing the study to limit the impact of attrition on data collection. It is recommended that the finger food menu is trialled over multiple mealtimes and/or implemented across multiple wards to limit attrition caused by ward moves and discharges.

Future research should also provide flexibility for data collection periods to support maximal data collection points.

The study showed a limited change in nutrient intake across two days of data collection for those who trialled the finger food menu. This study was unable to comment on the longer-term impact of finger foods, based on a short-term follow-up time. What is unknown is how patients would respond to finger foods over time, whether habits would stick for a prolonged period and whether finger foods as an intervention would be considered for use in home settings or long-term care settings based on patients' use of them in hospital.

7.4.2 Was data collected reliable and valid?

Due to the small sample size for this feasibility study, the median value was reported to enable comparisons between dietary intake measures for the standard meal and finger food meals and non-parametric tests used to see the difference between the standard and finger food meal. Due to the wide spread of data the median was appropriate as it was not affected by the wide range in dietary intake values and outliers. A future study should consider the most appropriate statistical test based upon results. It is likely that calculating the mean value with a much larger sample size will provide the opportunity for further statistical testing, depending on the distribution of data points.

Collecting dietary intake data in hospital can be challenging. However, using digital photographs as a method for estimating percentages of food waste meant that dietary intake could be more easily measured in the hospital environment. Collation of dietary intake in hospital through estimates has been shown to be a valid method to estimate energy and protein against plate weighing (Bjornsdottir et al. 2013). In a future study, resources and researcher time will need to be accounted for in considering the increased data set that will be collected.

A future larger trial will require multiple researchers to collect and collate dietary intake data. This feasibility study showed that the dietary intake measure had good inter-rater reliability with little training. This is in line with similar findings by Navarro et al. (2014), who showed good inter-rater and intra-rater reliability of plate waste estimations using the Comstock scale (Comstock et al. 1981). Navarro et al. (2014) used 106 lunch trays of newly hospitalised patients, assessed independently by two trained dietitians.

Other studies addressing the inter-rater reliability of plate waste using digital photographs have shown that training does not impact on accuracy or reliability of estimations (Parent et al. 2012). In the study by Parent et al. (2012), four researchers were asked to estimate plate waste from digital photographs. Two researchers had received some training on plate waste estimation, and two were based off-site and only received a postal audit with reference plate images to assist in estimations. Encouragingly, this means that timing or geographical location of researchers is unlikely to be a challenge in a future study.

7.4.3 What are the most appropriate outcome measures?

Dietary intake was calculated from plate waste estimations (recorded from digital photographs) which showed good inter-rater reliability. Interviews with staff participants highlighted the importance of nutrition for hospital patients. They discussed the importance of ensuring that patients received a ‘balanced meal’ and that they gained enough nutrition. However, they acknowledged that patients had little awareness of the nutritional intake of food when in hospital and chose foods with no regards to nutrition.

Nutrition was considered as low importance in interviews with patient participants. Most patient interviews displayed their lack of awareness of nutrition when in hospital. Interviews suggested that patients were less concerned about nutritional intake and more concerned about fulfilling their food preferences, the meal environment and food quality. Therefore, before deciding to proceed with a full trial it will be important to choose outcome measures that support the best clinical outcomes for the patient participants in receipt of the intervention.

There appears to be no ‘core outcome set’ or expertly defined list of outcomes used to evaluate interventions to improve dietary intake in acute settings (COMET Initiative 2020). The integrative review in Chapter 2 showed that published papers used varying outcome measures to evaluate the use of finger foods in long term care settings; for example, food intake and patient weight as well as quality of life, independence and wellbeing (Heelan et al. 2019). Wellbeing was measured using a reliable tool in only one study included in the integrative review by Barratt et al. (2001) who used Dementia Care Mapping. Dementia Care Mapping (DCM) is an observation tool used to measure wellbeing and the lived experiences of people with dementia (University of Bradford 2015). The tool requires observers to record two codes every five minutes during the observation period: a behaviour category code, which records what the person was doing for the five minutes, and a mood and engagement value which describes the engagement of the person with dementia and whether their mood was positive or negative. However, this tool is not validated for use with other patient groups.

Good nutrition can be associated with improved quality of life, better functioning, preventing malnutrition and associated disease and supporting physical and mental wellbeing (Amarantos et al. 2001). Quality of life is a multidimensional concept defined as a person’s view on their position in life, accounting for the culture and value systems in which they live in relation to their goals, expectations and standards (Pequeno et al. 2020). The complexity of the concept means that assessment of quality of life must account for different components including physical health, psychological state, level of autonomy, social relationships and beliefs. Typically instruments for assessing quality of life are either generic or specific to function (Pequeno et al. 2020). It is difficult to ascertain a change in quality of life in acute settings due to the likely short duration of stay on the ward and additionally the interrelated factors such as acute illness, which is likely to have a bigger impact than the food they ate on a quality-of-life scale.

Considering the findings from the qualitative interviews, in which participants focused on food quality, visual appeal and familiarity of food, food satisfaction could be considered as an important measure. Food satisfaction is often used to evaluate inpatient hospital food services (Dall'Oglio et al. 2015). A systematic review by Dall'Oglio et al. (2015), which aimed to review the literature regarding patient satisfaction with hospital food service, showed that the measurement of patient satisfaction requires simple, sensitive, validated and reliable instruments. It described that satisfaction ratings can be obtained using qualitative methods such as interviews or focus groups or using a questionnaire method. Collecting data through a questionnaire allows the effects of food changes to be monitored and highlight areas that require modification. Questionnaires are often useful to use alongside interviews to enable more detail about the modifications required to be made. A future study may benefit from using a quantitative measure alongside qualitative interviews.

Acute care food satisfaction has been measured by different tools and instruments. These are often adapted for specific contexts and studies; however, they need to be validated. In addition, any instrument used with people with communication or cognitive difficulties will need piloting to ensure that it can be accessed and remain validated if presented in an alternative format. A tool highlighted by Dall'Oglio et al. (2015), with good construct validity and reliability is the 'The Acute Hospital Foodservice Patient Satisfaction Questionnaire' (Capra et al. 2005). This questionnaire uses 16 statements relating to four factors describing food quality, meal service quality, staff/service issues and food environment. This enables attributes from each factor of foodservice to be compared.

Staff interviewed felt that finger foods would support rehabilitation of eating by encouraging patients to eat independently rather than being fed by staff. The therapeutic and rehabilitative benefit of finger food has not been previously reported (Heelan et al. 2019). In a future study evaluating the use of finger food in people after stroke, this may require further exploration considering the nature of the stroke rehabilitation population. Measuring change and showing the rehabilitation benefit of a nutritional intervention can be challenging. Westergren et al. (2001b) evaluated eating difficulties and the need for assisted eating in patients admitted for stroke rehabilitation using structured observations of eating performed at a regular meal or a test meal and the Katz Activities of Daily Living (ADL) index. The Katz ADL index developed by Katz et al. (1970) summarises an individual's overall performance based on six functions: hygiene; dressing and undressing; ability to go to the toilet; mobility; ability to control bowels and bladder; and food intake (Westergren et al. 2001b). Performance is based on whether the person is dependent or is completely independent with eating and therefore cannot easily measure small increments of change. Medin et al. (2011) examined eating difficulties among stroke patients using structured observations and estimated the degree of independence using The Barthel Index (Mahoney 1965). The Barthel Index includes rating independence on ten personal activities by gathering information from healthcare staff involved directly in the care of patients. The Barthel Index scores patients on their ability to perform tasks either independently, with some assistance, or fully dependent, but does not score items for when only supervision is required.

It is unlikely that the Katz ADL index or the Barthel Index will be sensitive enough to detect a change in independence with feeding when trialling a finger food menu. Findings from mealtime observations revealed changes in the type of support that participants required but didn’t suggest that participants became fully independent with feeding. To measure rehabilitation gains more consistently in a future trial, a structured observation tool could be considered. Medin et al. (2011) describe a tool which measures nine items relating to feeding including sitting position, managing food on the plate, transporting food to the mouth, opening and closing the mouth, manipulating food in the mouth, swallowing, food consumption, reduced alertness and aberrant eating speed. This tool shows promise, but the version of this instrument is based on an unpublished protocol and has not been tested for reliability (Westergren et al. 2002b). Before use in a future larger trial reliability and validity should be assessed.

In a future study, the research question should drive outcome selection. Dietary intake is an important factor and closely related to other clinical outcomes such as risk of malnutrition, rehabilitation potential and length of stay in hospital. Although many participants within this study sample had a low MUST score on admission to the hospital, eating sufficient nutrition to meet requirements remains a priority for all patients and is key to supporting rehabilitation effectiveness after stroke. All patients need to maintain their weight during stroke rehabilitation and need to eat sufficiently to do this. Dietary intake outcomes are important to clinical commissioning; however, the interviews raised interesting point to the importance of secondary outcomes such as food satisfaction and rehabilitation outcomes which are prioritised by patients and could impact on adherence and attrition which were issues in this study.

7.5 Intervention content and delivery in the ward environment

The mealtime observations and data from interviews demonstrated how the intervention was used on the ward. Understanding how the intervention worked and if it worked as intended informs whether and how it should be used in future. The data provided information on processes that facilitated and/or prohibited the intervention's use on the ward. This information can be useful for follow up trials (Campbell et al. 2007). For example, if an intervention is effective, understanding the process for success can support the intervention's application to an alternative context (Campbell et al. 2007). Conversely, if the intervention is deemed ineffective, the reasons for this can be identified, e.g., whether the intervention was implemented as intended or inadequately developed.

Access to the finger food provided during the intervention period was shown to be used in different ways from that presumed by the PhD candidate. Ongoing support from family and members of staff was deemed essential in supporting the implementation and success on the ward. In addition, personal belief systems of the staff and patient participants influenced the acceptability of the intervention on the ward. These key areas are further discussed below, before leading to key recommendations for a future trial.

7.5.1 Accessing finger foods

Finger foods provided participants with the option to eat food without using cutlery and therefore altering 'meal access' described by Keller et al. (2014) as one of the key influencing factors to food intake. Mealtime observations showed that finger foods were accessed by participants using both their hands and cutlery, which was an unanticipated finding. These findings challenged the original definition of finger food provided in the introduction: 'finger foods are foods presented in a form that are easily picked up with the hands and transferred to the mouth without the need for cutlery'. Participants were provided with cutlery on their tray on serving as part of standard care, which could have facilitated the additional use of cutlery. Indeed, the study by Visscher et al. (2020) on providing finger foods as snacks to care home residents also found that frequently staff provided cutlery to support residents to eat finger food. Visscher et al. (2020) reported that this did not adhere to the study protocol. The qualitative data from this feasibility study supported further in-depth knowledge of why cutlery was used and whether changes to intervention protocols are required in the future.

Qualitative interviews indicated that whether participants used their hands or cutlery was impacted by their familiarity or having finger foods at home. Some participants described using their hands to eat finger foods as 'something they had always done'. Other participants found eating with their hands in hospital 'strange'. The idea of 'reconnecting with prior eating habits' as described in the conceptual model of eating difficulties in people after stroke by Klinke et al. (2013) is reinforced here (illustrated in Figure 1-2, page 31). Klinke et al. (2013) suggested that a positive consequence of the changes caused by stroke will be people attempting to balance prior eating habits into their new reality. This suggests that those who predominantly eat with using a knife and fork will aim to continue to use a knife and fork after their stroke.

People after stroke with physical impairments found using their hands to eat generated additional complications. In interviews, finger foods were described by one participant as 'good in theory but challenges in practice'. 'Challenges in practice' mostly related to difficulties opening packaging and accessing food due to physical impairments. The BDA nutrition and hydration digest encourages hospital food packaging to be easily accessible but does not make specific recommendations for people after stroke who are likely to have physical impairments (British Dietetic Association 2017). The impact of food packaging in hospitals has previously been explored in a study by Bell et al. (2020) in Australia which aimed to evaluate the impact of food packing on the consumption of hospital food. However, being conducted in a simulated lab environment means that the complexity of a hospital meal with other environmental demands was not replicated.

The access to finger foods has important implications to whom finger foods should be offered in the future and for the outcomes measured. Serving finger food with the option for using cutlery is important alongside ensuring that packaging and hand wipes or hand washing is accessible. The potential rehabilitation and therapeutic gains of using finger foods may impact contexts in which they are used and widen populations who may benefit.

7.5.2 Support with independence

Initially, the introduction to finger foods section of this thesis related to finger foods as supporting independence with meals as a benefit for people trialling them. However, patients interviewed discussed how they relied upon family and friends for support with mealtimes. One patient interviewed felt that if full support was available from family to set up a meal and help with feeding, then finger foods were not required. Indeed, some patients interviewed did not always acknowledge the support that they had received from staff throughout their meal. In some cases, staff members encouraged patient independence with eating finger foods with their hands. Other members of staff, themselves not used to eating with their hands, were likely to make negative comments about the food or method of eating, which may have affected the patients' willingness to try it.

The culture of acceptance of support with activities of daily living can be drawn upon. There is some evidence to suggest that that older adults in later life are more satisfied with receiving support with their eating and drinking than younger patients (Shune 2020). However, the interview study focused on younger adults as those 18-30 and is therefore unlikely to be fully representative of the typical stroke population (Shune 2020).

Patient participants observed referred to the embarrassment of lacking control over mealtimes and making a mess. Some participants saw finger foods as a method of gaining some control with eating again and with potential to avoid mess. The embarrassment of becoming dependent on others with self-care such as washing and dressing and feeding after stroke has been previously described in the literature. The qualitative study by Kitson et al. (2013) interviewed 15 stroke survivors with inpatient hospital experiences of fundamental care from the UK. Kitson et al. (2013) revealed the psychosocial and emotional impact of becoming dependent on physical needs after stroke. Kitson et al. (2013) showed that for some, experiences are mediated by staff members and enable patients to feel positively supported and respected or negatively embarrassed and humiliated. This has been further described as fundamental care (Bridges et al. 2010). Bridges et al. (2010) conducted a systematic review of qualitative studies on older peoples' and relatives' experiences in acute care settings which showed that staff need to maintain focus on patients' responses to care and must respect patients' identities and needs in order to produce positive experiences for patients and their families. In a future study, consideration to accurately measuring patient experience should be considered.

7.5.3 Personal belief systems and impact on acceptability of using finger foods

Culture is defined as a set of personal beliefs of a group of people at a particular time. Cultural influences were a key theme highlighted in qualitative interview findings with regards to the implementation of finger foods on the stroke rehabilitation ward. These influences impacted on whether patients and staff found it acceptable to eat foods with their hands. The perception of eating and mealtimes as simply a provision of the nutrition required to keep people alive has long been replaced by the importance of social, cultural, behavioural, and symbolic meanings of food. Individual decisions about food are seen as central to daily living and personal identities (Kayser-Jones 1996).

Personal belief systems are often influenced by culture. It is important to consider that within a 'different' environment, such as a hospital, a different culture may exist. In hospitals, culture focuses on patient safety and quality (Amella and Aselage 2012) defined as "preventing patient harm and delivering quality care" (Mitchell 2008 para. 6). Staff beliefs regarding patients using their fingers to eat was identified from mealtime observations. Staff beliefs appeared to influence participants' access to food. This impacted on whether eating with the hands was encouraged or discouraged. Similarly, in the study by Visscher et al. (2020), the attitude of staff serving finger food was reported to influence the acceptance of finger food for nursing home residents with dementia. Previous studies have shown that patients know that staff preferences are valued more than their own (Palacios-Ceña et al. 2013). Therefore, Visscher et al. (2020) recommend that members of staff are involved in finger food development to support acceptability.

Generation and age of patients were raised by staff as key in influencing food choices, based upon culture and eating ability, e.g., absence of teeth. Participants who were patients described how being older impacted on the texture of food they required. Participants said that they wanted food that was easier to chew as they got older. Future finger food menus should consider how food can be served to meet generational needs.

The future of providing finger foods needs to consider the cultural values of the individual patient to ensure person centred, relational care is provided. These cannot be pre-determined by staff who may choose to decide which patients will get offered types of food.

Staff members interviewed raised the idea that finger foods could be considered 'childish' in terms of the way they were eaten, and the types of food offered. Staff felt 'rude' in associating the meals served to adults as 'childish'. The idea that finger foods could be considered 'childish', being a barrier to implementation was highlighted in a French opinion article by Godart et al. (2017). Finger foods are typically used for 'baby-led weaning' in the UK and are recommended as the first type of solid food to be offered to infants to encourage self-feeding from the outset (Rapley and Murkett 2008). Using the same name associated with the 'baby-led weaning' tool may have supported staff's connotations. Patient participants did not allude to child-like connotations; however, they highlighted the importance of ensuring that food they were eating made as little mess as possible.

Similar to the appearance of finger food, the appearance of puréed food is often associated with 'baby food'. These connotations were reported in a qualitative interview study with 15 consumers (and five family members) from long-term care settings in Canada (Keller and Duizer 2014). Although recommendations for puréed food are made to support swallowing for people after stroke, patients referred to being fed purée food with 'a bib around my neck' to feeling 'like a baby'(Moloney and Walshe 2018). The study by Keller and Duizer (2014) revealed the importance of food's appearance to patients feeling that they were being treated with dignity and suggested that puréed food should be made distinguishable using colour to enhance its appearance. The 'child-like' connotations with finger foods should be addressed when training is provided for the provision of finger foods in care settings to mitigate the possibly conflicting viewpoints of staff and patients.

Future menu developments should consider staff's opinions about appropriate foods for the menu. In addition, a future study should consider relatives' opinions. The abstract by Tuinier et al. (2014) reported survey results from caregivers' and relatives' opinions of finger foods trialled in a Dutch care home. Interestingly, relatives' and caregivers' opinions of finger food slightly differed.

7.5.4 How did intervention work in the stroke rehabilitation context?

The findings from this feasibility study showed that it was possible to implement the finger food menu across lunchtimes on the stroke rehabilitation ward. By identifying the factors that facilitated and impeded adoption, it was possible to draw conclusions over which strategies would support future implementation of the menu.

Mapping the findings from the mealtime observations to the I-PAIRHS framework highlighted the importance of the context and the PhD candidate acting as a facilitator to support the successful implementation of the intervention. Engagement with clinical and catering teams when developing the finger food menu allowed the menu to be designed to fit the ward setting used for this study, however there were ongoing challenges with staff not being aware of the reason for using finger foods and their own beliefs about eating with fingers impacting whether patients felt comfortable using their fingers. The presence of the PhD candidate during the data collection period and open communication channels between the PhD candidate and key leaders, including the ward manager and catering leaders, meant adaptations to the menu delivery could be overcome, such as menu items becoming unavailable or participants requesting standard menu items during the implementation phase.

Attention must be paid to the context where the intervention is implemented because interventions tailored to fit a specific context work best (Craig et al. 2008). MRC complex interventions guidance suggests that understanding the context is part of a feasibility study (Craig et al. 2008). The findings from interviews with members of staff in this feasibility study acknowledged the complexities of making change within the hospital system and the requirement for this flexible intervention to fit with the conventional system.

Previous studies evaluating the processes involved in the implementation of mealtime interventions in hospitals have acknowledged the importance of the culture and the context in promoting successful change (Ottrey et al. 2018). Ottrey et al. (2018) highlighted the requirement to recognise the complexity of providing a hospital food service that better supports patient care, indicating the importance of addressing both patient-centredness and system factors. The model presented by Ottrey et al. (2018) shown in Figure 7-1 presented a disharmonious relationship between patient centred care and the system due to time, awareness, accountability and responsibility of staff. Time related to the busyness of staff, which affected how tasks and quality care were provided and impact of delays and interruptions of food service which impacted patient mealtime experience. Lack of awareness of mealtimes by clinical staff were perceived to influence a patient's mealtime experience and meant that other's mealtime work such as food service staff work was underappreciated. Accountability and responsibilities to complete meal-related documentation such as food and fluid charts were reported to interrupt on patient mealtimes and undermine patient centred care. Ottrey et al. (2018) demonstrate the challenges staff face when trying to support patient centred care and concludes that efforts to address inadequate food intake in hospital needs to consider food service process and nutritional care as complicated with complex interactions. This model helps to explain the constraining system factors that exist with implementing patient centred nutritional care, of which some were acknowledged by clinical staff in this study. Addressing these factors will likely support implementation of a finger food menu in a 'real-world context'. The factors presented by Ottrey et al. (2018) relate to the context and culture of the ward environment, which are considered by implementation science literature to support an intervention to be fully implemented into clinical practice. Staff need to be given the power and ability to recognise what patients need in terms of nutrition, culture and physical ability, and to do this they also need to recognise their own views on eating and how this could impact the care they give to their patients.

Prior mealtime intervention studies have focused on the context supporting implementation success. However, this feasibility study focused on the facilitator as the key to implementation success. The PhD candidate could be described as an 'internal facilitator', as she was designated to the individual site and had good working relationships with the ward and catering staff. The PhD candidate was primarily known to staff as an SLT and subsequently as a researcher. Within the I-PARHS framework, the facilitation construct is described as an active ingredient to implementation success (Harvey and Kitson 2015b). Facilitation of an intervention is a process that is dependent upon the person (facilitator) acting as a change agent. The facilitator requires appropriate skills, personal attributes, and knowledge to take on this role. The guide for applying the PARIHS framework for implementation looks further at the role skills and attributes required for a successful facilitator (Stetler et al. 2011). Stetler et al. (2011) describe flexibility to recognise individual situations, having an approachable nature so that staff feel comfortable coming to support and confidence to be able to make changes based upon what is being seen within the context as important skills. These skills should be recognised in a future facilitator supporting the implementation of a finger food menu.

The findings from this study also supported the need to engage clinical and catering teams early and to provide appropriate training and awareness of the intervention. Previous studies evaluating the use finger foods shown in the integrative review by Heelan et al. (2019), highlighted the importance of involving team members in the development and design of a finger food menu. This supports the menu to fit the context the menu is developed for. In addition, members of staff who have knowledge about the intervention and reasons for using it and who are available on the ward can act as champions for the intervention. A champion can be described as a local visionary who uses expert knowledge to persuade others about an idea of project, they can be seen as advocates for change and used to motivate others (Cranley et al. 2017). For this feasibility study, the PhD researcher acted as a champion for the study, by supporting catering staff on the ward to deliver the menu items, offering the menu to participants on the ward and motivated to engage ward staff in conversation about the intervention. A future larger study should consider the role of champions for both clinical and catering teams to motivate the wider stroke team to adapt to change.

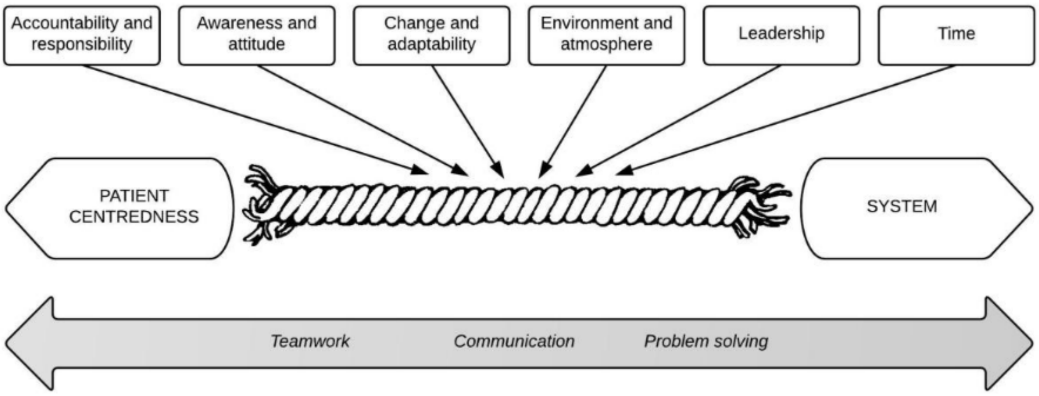


Figure 7-1 Model illustrating tension between patient centredness and system (Ottrey et al. 2018)

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7.6 Informing a future evaluation

Based upon the results of the feasibility study, this section considers what a future trial design for the evaluation of a finger food menu should look like. The feasibility study showed the importance of undertaking the study within the 'real world' context and the importance of using mixed methods data. Strategies that influenced success of implementation are further discussed and should be considered for a future trial.

7.6.1 Strategies to support successful implementation

Factors relating to the context and facilitator role merit attention in a future design of a study. The intervention needs to be refined to fit within the local context and organisational policies and should be implemented with full support and engagement from catering and clinical teams. The findings from this work reflect that support needs to be gained at an individual level, including staff working on the ward, but also at a team and organisation level to support the changes to be sustained. The findings point towards a number of organisational conditions which would support the implementation of the intervention in another context. A facilitator should be available throughout the implementation stage, acting as a role model for using the intervention and adapting the intervention to fit with the context.

Further research across a wider range of settings will enable these strategies to be considered and enhance their transferability. Further research will enable the links between the context, facilitation, implementation processes and outcomes associated with the implementation of a finger food menu to be described.

7.6.2 What the mixed methods analysis adds

A mixed methods approach was used to enable deeper understanding about certain aspects of the research (Creswell and Plano Clark 2018) and to satisfy all objectives of the study (Craig et al. 2008). The integration of both quantitative and qualitative findings provided several valuable conclusions and insights into the data and considerations for a future, definitive trial.

The mixed methods component of this study has provided additional insights into the provision of finger food and this methodology has important strengths for future research. The use of qualitative interviews at bedside with patients and with members of staff provided valuable insight and could be complemented by interviews with relatives in the future. The collection and analysis of both types of data provided a unique insight into the use of finger foods in a complex environment, which has not yet been fully evaluated.

The qualitative data provided further insight into patient experience and acceptability of the intervention to enrich the current understanding and a future study design. However, there were key findings in the qualitive data that were not included in the mixed methods analysis. The qualitative data revealed much richer descriptions that answered different research questions to the quantitative data and therefore were not ideally aligned to integration. For example, the amount and time of support required by paid nursing staff or family members, and the extended experiences of patients and staff was not something collected within the quantitative data. The qualitative data also provided evidence which was not considered within the quantitative data collection and therefore would have been missed, e.g., safety considerations. To fully explore this phenomenon quantitatively, a future study should consider valid and reliable outcome measures to obtain a wide range of data on the topic.

It is anticipated that a future study would benefit from a mixed-methods approach to understand the context in which the intervention is being implemented and anticipate the views and experiences of participants involved. A changing environment, including a global pandemic during the write up of this study, will have potentially altered the views of patients and staff. There is emerging literature on the effect of social isolation for care home residents who had limited visitors during the pandemic (Abbasi 2020). At the time of writing, hospital visitors are severely limited, and this will have impacted the family support at mealtimes on which some patients rely heavily, as this study has shown.

The use of both quantitative data and qualitative data in an evaluation also supports understanding the process of delivering an intervention (Bauer et al. 2015). A process evaluation is an approach to understand the factors influencing the implementation of an intervention in the context of trial design and understand how the intervention was delivered (Moore et al. 2015). Quantitative data can be used to test causal pathways and qualitative data used to better understand complex pathways or mechanisms. A process evaluation enables researchers to understand whether the effects of the intervention have been impacted by weakness in design or because the intervention was not properly implemented. Process evaluations can be used during the feasibility testing stage as well as during effectiveness evaluations. During effectiveness evaluations, process evaluation can be used to understand what changes are required when scaling up from feasibility or pilot testing to a full-scale evaluation (Moore et al. 2015). For example, accounting for a greater variation in participants, context and practitioners involved. Even if factors known to affect the implementation of an intervention are identified in the feasibility stage, a process evaluation is recommended alongside the full trial to capture new problems which are likely to emerge (Moore et al. 2015).

7.6.3 Study timings

To fit with the PhD candidate's clinical and academic commitments, this research study was designed to collect data over lunchtime meals only. Those interviewed who declined to trial finger foods during the lunchtime meal on either one or two occasions reported that they would typically have a main meal at lunchtime and therefore did not perceive finger foods as a main meal and felt trialling finger foods would disrupt their 'usual' routine. A future study should consider offering the finger food menu over different mealtimes and consider whether this has an impact on dietary intake.

7.6.4 Safety

There were no adverse events regarding safety of the intervention disclosed during this feasibility study; however, staff raised safety concerns during interviews which should be monitored in a future study. These included choking. Some considered finger foods to be safer than standard meal items offered due to the food already be cut into bitesize portions. Some saw a similar level of risk to standard meal items if items such as fruit pips were offered to patients unable to manage them. The understanding that patients at risk needed to be monitored by staff was central to the management approach.

In addition, staff spoke about monitoring of the temperature of food to make sure it wasn't too hot to be eaten with the hands and had not gone cold and be left out too long. A future study should include a clear process for staff to follow in case of a safety incident or serious adverse event (SAE) that are described by the Health Research Authority as events that are as a result of the research procedures or unexpected (not listed in the protocol as an expected outcome) (Health Research Authority 2020).

7.6.5 Informing a future economic evaluation of cost and benefits

The BDA digest states that menus provided in hospital should provide 'good nutritional value for money' and promote food as medicine (British Dietetic Association 2017). Decision makers are interested in the effectiveness and cost effectiveness of clinical interventions (Edwards and McIntosh 2019b). NHS Trusts are under pressure to save money alongside improving food standards in line with the national Government food and drink strategy (Department of Health 2015). Freedom of information requests in 2018 revealed the cost of providing hospital food per inpatient per day was £6.10 - £9.98, however, it is acknowledged that variation exists between hospital Trusts (Department of Health and Social Care 2012).

The complex interventions framework does not fully describe methods for conducting an economic evaluation of a complex intervention (Craig et al. 2008). However, Craig et al. (2008) acknowledge that within an economic evaluation it is important to understand what interventions are cost effective and how they are cost effective (Edwards and McIntosh 2019b). Although cost-effectiveness analyses are the most common approach within an economic evaluation, this analysis is limited by only being able to focus on a single outcome (Kelly et al. 2005). Therefore, the National Institute of Health research has now acknowledged the need to evaluate the wider societal costs and benefits associated with interventions and considers use of a cost consequence analysis to support this (NICE 2011).

Considering the benefits of a complex intervention of the provision of finger foods a cost consequence analysis was conducted as a way of evaluating interventions with more than one outcome and measure change along multiple outcomes. From the perspective of the catering company, overall, food provided on the finger food menu cost less than the food provided on the standard menu. Mean food costs for the finger food menu per person, per meal were reported as £1.59 compared to £1.69 for the standard menu.

Previous studies evaluating the use of finger foods in long term care settings reported conflicting results regarding the cost provision of finger foods offered (Heelan et al. 2019). None of the studies provided a robust economic evaluation (Heelan et al. 2019) or suggested from which perspective their costs were associated which makes it difficult to rationalise the results. There are limited nutritional interventional studies that report an economic evaluation as a primary outcome. This is likely due to the difficulties in assessing relevant outcomes. Elia et al. (2016) conducted a systematic review of the costs and cost effectiveness of using oral nutritional supplements. Within this review, from the 19 randomised control trials included, clinically relevant benefits included reduced mortality, improved quality of life, reduced rate of infection and functional limitations (Elia et al. 2016).

A future trial should consider data collection for other identified costs outlined in the cost consequence analysis. A limitation to using a cost consequence analysis in a follow-up study is that it cannot easily compare with other nutritional interventions. A cost consequence analysis typically provides a table of costs and consequences as opposed to one outcome. Cost-effectiveness comparisons for single outcomes within the CCA framework can be produced (Kelly et al. 2005). A full economic evaluation is warranted, considering the longer-term consequences and whether these can be monetised. Future economic evaluations of using finger foods in hospital should consider additional benefits or consequences to participants. Such data were not collected for this small study because of the short period of time in which participants were enrolled in the study.

Staff time was considered as an indirect cost of the provision of finger foods. It was hypothesised that allowing patients the ability to access food more independently would reduce staff time required to feed patients. A future study should consider how staff or visitor time can be monetised.

Despite finger foods providing more independence to some participants, support provided by staff and family was key as identified in the interview study. Participants discussed how reliance upon a family member or friend over mealtimes supported a more natural approach to eating. Support from staff was particularly important within the meal set up and preparation tasks, such as opening packaging and supporting with handwashing, which was not always a priority for staff as discussed in interviews. Mealtime assistant volunteers were not utilised on the study ward. On other hospital wards, mealtime assistant volunteers typically conduct tasks such as preparing patients for meals. The literature suggests that mealtime assistant volunteers do not necessarily support the increase in energy or protein intake (Roberts et al. 2017); however, patients appreciated their support because volunteers had the time to wipe patients' hands before eating and prepared them for the meal (Roberts et al. 2014). Future research should consider the role of mealtime assistant volunteers, where they exist, in supporting implementation of finger foods on the ward.

7.7 Additional learning points

Findings from this feasibility study provided important information for a future follow up study. Aside from the feasibility results, interesting and important patterns in the data were found with regards to general dietary intake across the sample population across lunchtime meals. In addition, the measure of plate waste using before and after photos was proven to be a tool worthy of further implementation in clinical practice and in research. These two key points are further discussed here.

7.7.1 Range of dietary intake

As documented in Section 5.6.3.1, Table 5-6, median energy in kcal and protein intake across all mealtime observations was low and did not meet guidelines set by from the British Dietetic Association (BDA), detailed in the food and drink standards in NHS hospitals set by the UK Government (Department of Health 2014). Guidelines recommend energy and protein requirements for hospital food menus based upon two categorical groups (British Dietetic

Association 2017). A definition of 'nutritionally well' and 'nutritionally vulnerable' patients is outlined in Table 7-1 (British Dietetic Association 2017), showing recommended energy and protein intakes per day and per meal.

Table 7-1 Nutritional guidelines for 'nutritional well' and 'nutritionally vulnerable' hospital patients (British Dietetic Association 2017)

Nutrient	**Nutritionally well**	**Nutritionally vulnerable**
	Patients with standard nutritional requirements and normal appetite	Patients with standard nutritional requirements but with poor appetites, unable to consume normal quantities at mealtimes, or with increased nutritional needs
Energy (kcal) per day	1840-2772	
Protein (g) per day	56	66-83
Energy (kcal) per meal	500	800
Protein (g) per meal	15	25

Based on the nutritional guidelines in Table 7-1 participants did not meet lower limits of energy requirements (based on kcal) for nutritionally well groups. For both the standard and finger food menus, participants met the lower limit requirements for protein but did not maintain levels for the nutritionally vulnerable group. Median values of protein were lower in the finger food menu trials than with the standard meal trials. One factor that may have influenced this is the use of generic requirements as opposed to individual requirements calculated on body weight.

Suboptimal energy intake of patients after stroke in hospital has been reported elsewhere in research studies. A prospective study by Nip et al. (2011), carried out in South London, showed that compared with national recommendations, acute stroke patients consumed adequate protein at both hospital admission and just prior to discharge but suboptimal energy intake. Foley et al. (2006) more accurately demonstrated participant energy requirements using body weight and showed that well-nourished, hospitalised, acute stroke patients in Canada consumed 80% to 91% of their actual energy requirements during the first three weeks of admission with one quarter of participants receiving less than 80% of their requirements putting them at high risk of malnutrition. A more recent audit of nutritional intake in UK hospitals showed that from 93 hospital patients admitted to a range of inpatient wards across a hospital in the South West of England, significantly lower levels of energy intake was observed (Pullen et al. 2018). However, this audit also revealed that the amount of energy provided by meals chosen by patients from the hospital main menu did not contain sufficient amounts of energy based on the BDA guidelines (Pullen et al. 2018). Considering that NHS Trusts are responsible for meeting the nutritional needs of all patients in hospital (Department of Health 2014), menu options require ongoing monitoring and tailoring for individual patients.

Providing fortified foods as part of a finger food menu could be considered to ensure standards for all nutrients are met. The use of fortified snacks to enhance food intake has been reported elsewhere, including cakes, bread, biscuits, or ice cream, of which all of which could be presented as a finger food e.g., ice cream in a cone. A systematic review evaluating the effectiveness of fortified foods to increase the dietary intake of hospitalised older adults concluded that this may be an acceptable, effective and economical strategy to meet the nutritional needs of older adults in hospital (Mills et al. 2018). This review made no association with the fact that these types of foods could be eaten with their hands or more easily accessed, which may have impacted patient acceptability.

Factors affecting dietary intake in hospital are multifactorial. Patient factors have been shown to have a profound effect on food consumption in hospital. Nausea, acute infections and higher BMI have been shown to predict poor nutrition across patients in hospital (Leistra et al. 2011). Patients interviewed in this study described how appetite impacted on food desire and intake. Patients interviewed said that they didn’t necessarily always feel like a meal and it depended upon whether they were feeling unwell or what else they had been doing in the day. One participant described how initially during the acute stages of stroke, appetite was limited, however appetite increased as rehabilitation progressed. Reduced appetite could provide some evidence as to why intake varied so widely but is difficult to evaluate due to the complexity of inter-relating factors.

Poor appetite in hospitalised older adults has been recently reported by measuring appetite using the Simplified Nutritional Appetite Questionnaire (SNAQ) tool (Cox et al. 2020). In future research it would be important to fully understand what is impacting on patient participant’s food intake; whether or not finger foods support changes in appetite and whether this does correlate with different stages of rehabilitation. This will enable further understanding of who would benefit most from the intervention and at what time point.

7.7.2 The future for automatically estimating dietary intake

This study successfully used digital photos to estimate dietary intake. In hospital, accurate monitoring of patients’ food intake is used to identify patients at risk of malnutrition. However, accurate collection of food intake is a difficult and resource-intensive task. Typically, nurse-completed food record charts are incorrect or incomplete for a number of reasons, including competing responsibilities and tasks at mealtimes, inadequate training or understanding of the importance of food record charts, or removal of food tray by catering staff before nursing staff have observed intake (Xia and McCutcheon 2006). Little is known about patients' consumption of different food components whilst in hospital and how this links to risks of malnutrition or acute deterioration.

In research studies, evaluating the effectiveness of new dietary interventions is difficult due to researchers' inability to measure patient food intake quickly and reliably. Previous studies have used visual estimation, weighing plate waste on the ward and retrospective food recall to monitor food intake (Connors and Rozell 2004). These tools can be time consuming and disruptive in the ward environment, and recall can be subject to bias.

Digital photo images have been successfully used in hospital research studies to record food intake (Ofei et al. 2015). Results from this study showed that photos taken of a plate can be taken quickly and easily on the ward before and after a meal and then analysed manually away from the clinical area. However, this study's manual analysis method was time consuming and would not be suitable for real-time in clinical settings.

With larger data sets, future trials should investigate the feasibility of automating this procedure using artificial intelligence. Artificial intelligence to automate dietary intake calculations is a new technology, only briefly described in research papers, but one with the potential to improve the efficiency of randomised control trials with larger sample sizes. This technology appears to be in its infancy, with a conference paper reported by Lu et al. (2019) who has evaluated the development of a system to estimate the volume of the consumed food from a hospital plate and automatically estimate nutritional intake for each food type with a 15% estimation error (Lu et al. 2019).

This technology also has potential for use in clinical practice where an automatic photo detection application can be used as a more accurate, real-time measure to estimate food intake. There is potential to link this with diet analysis software to gain the full nutrient profile of food eaten and to evaluate diet diversity. Clinical staff could use this real-time data to highlight patients at risk of reduced dietary intake. There is also an opportunity to generate hypotheses regarding food components and their impact on the body.

At present, the development of this project has backing from professors in nutrition and computer science at the University of Southampton and interest from commercial developers. A group of undergraduate students are working to develop a prototype and a small fund won by the author of this thesis from the University of Southampton is being used to develop this project further. Once developed, this technology will require testing in a future larger trial.

7.8 Strengths and limitations of the study

All studies have strengths and limitations, which should be highlighted. Additional limitations relating to the feasibility findings in this thesis are presented in Section 5.10.

There are two main strengths of this study. Firstly, the use of mixed methods and integration of both qualitative and quantitative data collection methods has allowed full understanding of the intervention and to fully answer the research question. The qualitative interviews and observations highlighted feasibility issues that were not apparent in the quantitative data and will allow the intervention to be modified in a future trial.

Secondly, the design of the study was very pragmatic, working in line with current hospital procedures, which supported the implementation and introduction of a new intervention into the ward environment. This feasibility study addressed an area of research not previously fully investigated. There have been limited publications addressing the use of finger foods in hospital and it appears that finger food use in hospital is variable across Trusts. In addition, the use of finger foods with people after stroke is an under-recognised area and therefore warranted evaluation.

Prospective limitations to this study stem from the study being conducted by a lone, student researcher with time and budget restrictions. This impacted on the number of potential participants that could be consented to the study and time available for data collection. Despite this, the study aimed to ensure that enough data were collected to make an adequate decision regarding the feasibility of a future study. Conducting this study at a single site with one stroke rehabilitation ward means it was not possible or practical to conduct a separate control group alongside the intervention group or to randomise participants. The sample population for this study will limit the generalisability of the results but will nevertheless have collected valuable data for the future.

A limitation of the study was a high rate of missing data, which impacted statistical analysis. Reasons for missing data are further discussed in section 7.4.1 and should be accounted for in a future study with regards to sample size and study design.

This study is also limited by selection bias and the exclusion of participants who did not understand English. All information about the study was written in the English language and an interpreter was unable to be accessed due to the limited study budget. In addition, participants were involved in the intervention period for a brief period and interviewed only at one time point meaning the ability to judge sustainability of the intervention or experience of the intervention over a prolonged period is limited.

The inability to blind participants and the researcher in this study may have introduced bias. It is possible that participants or staff could have consciously or unconsciously changed their behaviours whilst being observed over mealtimes to reflect the anticipations or expectation of the researcher and being involved in the research study. The PhD candidate aimed to be reflexive during the qualitative research data collection to ensure a rigorous approach. However, because the researcher was heavily involved in the study, she may have influenced what the participants wanted to disclose about using the intervention on the study ward. Despite this, participants were still asked to give opposing views regarding the intervention and did so.

Chapter 8 **Summary of findings and future recommendations**

This feasibility study was conducted to address the gap in the current knowledge regarding the use of finger foods in acute care settings for older adults post stroke (Heelan et al. 2019). The study was framed using the complex intervention framework considering the complexity of hospital mealtimes with multiple interrelating components (Craig et al. 2008). This feasibility study utilised a pragmatic viewpoint which aimed to operationalise a finger food menu on the stroke rehabilitation ward, determine the feasibility of offering this alongside the standard menu, and determine associated costs and acceptability across patient and staff groups.

There were two main components of this feasibility study in which results were initially presented separately before quantitative and qualitative results were integrated within this chapter.

- **Chapter 5 presented results from the 'before and after' data collection with mealtime observations.** This component aimed to test the viability of conducting a future trial to evaluate the effectiveness of using finger food for people in hospital considering food intake and meal experience. It addressed research questions using quantitative data collection methods and observational field notes.
- **Chapter 6 presented findings from qualitative interviews**. This component consisted of qualitative semi structured interviews to explore patients and staff experiences and views of using finger foods on the stroke rehabilitation ward and to provide information to refine the study intervention.

Shanyinde et al. (2011); Bugge et al. (2013) report a useful framework for summarising findings from feasibility studies against 14 methodological issues. Table 8-1 summarises the key findings and evidence to support findings within this thesis.

Table 8-1 Summary of findings against methodological issues based upon (Shanyinde et al. 2011; Bugge et al. 2013)

Methodological issues	Findings	Evidence (Section in thesis)
Did the feasibility study allow a sample size calculation for the main study?	For a future study, based on energy intake as a primary outcome it is estimated 330 participants will be required (165 in each arm of the trial). Inflation factors, funding and researcher time will need to be accounted for.	A sample size has been estimated for a future study based upon 5% significance level and providing 90% power to detect an improvement of 25% in energy intake from having the finger food menu compared to the standard menu and allowing for 40% loss to follow-up. See section 5.9, page 178.
What factors influenced eligibility and what proportion of those approached were eligible?	Factors that influence eligibility rates were diet modification and age.	35% of patients screened were eligible. See section 5.3.2, page 143.
Was recruitment successful?	There was a sizable population willing to take part. Expected recruitment rates were met.	Recruitment rate into the trial reached an average of four participants a month and was completed on time. See section 5.3, page 141.
Did eligible participants consent?	There was a low conversion rate from eligibility to consent.	48% of patients approached by the researcher consented to study. Conversion rate was impacted by patient preference and study timings. See section 5.3.3, page 144.
Were participants successfully randomised and did randomisation yield equality in groups?	A future study should consider cluster randomisation at ward level.	Randomisation was not assessed as part of this feasibility study. See section 5.10.4, page 181.
Were blinding procedures adequate?	Blinding procedures were not possible in this study, due to using a lone, student researcher.	Blinding procedures were not fully assessed as part of this feasibility study due to single researcher undertaking the study. See section 5.10.3, page 181.
Did participants adhere to the intervention?	Most participants adhered to the intervention. Mealtime observations showed that finger foods were accessed using different modes to the intended use of the intervention.	Five participants declined to trial the finger food menu over two days. See section 5.2, page 140. Participants accessed food using both hands and cutlery based upon individual preferences and abilities. See section 5.6.5.1, page 162.

Methodological issues	Findings	Evidence (Section in thesis)
Was the intervention acceptable to participants?	Findings from interviews demonstrated the intervention was acceptable to patients and staff participants with suggestions for intervention development to increase uptake.	Participants described acceptability based upon familiarity of foods and type and presentation of food provided. See section 6.4.2 page 191 and section 6.4.4, page 195.
Was it possible to calculate intervention costs and duration?	Food costs associated with the intervention were calculated and compared with the standard menu. Additional indirect costs need to be considered as part of a cost consequence analysis.	Foods offered on finger food menu cost less than foods offered on standard menu. Full information on direct and indirect costs were reported See section 5.6.4, page 157.
Were outcome assessments completed?	There were high rates of missing dietary intake data especially over day three of the data collection period likely associated with study timings.	Full outcome measures were recorded for 61% of participants. See section 7.4.1, page 213.
Were outcomes measured those that were the most appropriate outcomes?	Dietary intake was an appropriate outcome measure. Food satisfaction should also be considered in a future trial.	See section 7.4.3, page 215 for full discussion regarding outcome selection.
Was retention to the study good?	Retention to the study was poor.	Full outcome measures could only be completed for 19 participants of the 31 recruited, see section 5.3.5, page 144.
Were the logistics of running a multi-centre trial assessed?	A single site was used for this study. Recruitment to a multi-centred trial needs to have a researcher with close links with the clinical team, knowledge of patient group and ability to support decision making.	Considerations to support recruitment in a multicentred trial is reported in section 7.3, page 207.
Did all components of the protocol work together?	Components had strong synergy.	The components and research processes of this study protocol worked well together. For example, participants were recruited to the study, offered the intervention, observed over mealtimes and a proportion of participants interviewed. Study timings for a future study require consideration.

This study provided increased knowledge to support the conduct of a future study, asking the question ‘can it be done?’. Pre-set criteria tested the success of the study based on the research objectives, including trial recruitment, protocol adherence and outcome data (Avery et al. 2017).

These criteria supported the researcher to understand whether the study could be done, should a future trial proceed, and if so, how? (Eldridge et al. 2016b). The researcher acknowledged that meeting all pre-specified criteria does not guarantee success in the main trial, and ongoing monitoring is required throughout the study (Avery et al. 2017). Failing to meet all criteria does not always mean that a future study is not viable; however, it does mean that modifications may be required to the study protocol. Outcomes relating to the pre-specified criteria are described in Table 8-2.

Table 8-2 Reported outcomes from pre-specified criteria

Pre-specified criteria for future study	Outcome
Recruitment rate into the trial reaches an average of four patients a month	Met
Data were collected for 75% of participants during day 3 of the trial	Unmet
Qualitative findings show finger foods can be successfully delivered and patients and staff generally report positive views regarding using finger foods	Met
Food intake measurements are feasible and reliable to use on the ward and therefore determined as a suitable outcome measure	Met
Costs to using the finger food menu are outlined and relevant to the consequences	Met

Of the criteria defined for the feasibility of a full-scale trial, the only target unmet was the retention to the study, in which the criteria stated that ‘Data were collected for 75% of participants during day 3 of the trial’. All other outcomes met the pre-set criteria for success. These pre-specified criteria for a future study provided confidence that generally the components of the protocol fit together well. There was an adequate, sizeable population to take part in the study. In most cases the intervention was acceptable, with some recommendations for future intervention development. The success of delivering the intervention in this study was supported by a menu developed to fit the context and the availability of an internal facilitator to aid the food delivery and make adaptions.

Based upon these results, Thabane et al. (2010) describe that the outcomes of feasibility studies are one of the following:

i) Stop - main study not feasible
ii) Continue, but modify protocol - feasible with modifications

iii) Continue without modifications, but monitor closely - feasible with close monitoring
iv) Continue without modifications - feasible as is.

As per the systematic approach to evaluating a complex intervention (Craig et al. 2008), this preliminary study has successfully advanced knowledge regarding the need for a future trial to fully evaluate the effectiveness of using finger foods for older adults after stroke in hospital. It is recommended that a future study should be conducted with minor modifications to the protocol to ensure successful recruitment, retention and implementation.

The following specific issues should be considered as alterations to the future trial:

- Consider a mixed methods study design, with randomisation of participants within clusters at either ward or site level. Consider appropriate study timings and study design to mitigate issues with missing data. Flexibility should be included with data collection periods. A process evaluation should be conducted alongside the trial to support scaling up of the intervention.
- Develop the intervention further to support those on textured modified diets, improve choices, ensure consistency with presentation and ensure that packaging is easy to open.
- Consider the eligibility criteria and study sample, based on the types of food offered within the intervention.
- Include interpreters to support the consent process and include a wider, more diverse sample. Continue to support people with communication difficulties in consenting to study through access to an SLT and using other non-written versions of consent.
- Ensure the recruiting researcher has prior good working relationships with the study site within a multisite trial. This thesis presents evidence that prior good working relationships can be helpful. This recommendation is desirable and will expedite progress in the early stages of a project.
- Ensure demographic data collection is appropriate to give enough detail, consider use of cognitive assessment or functional baseline assessment.
- Include measures to support blinding the researcher, e.g., to study groups
- Consider using other measures to measure food satisfaction and change in quality of life, independence with feeding and therapeutic benefit.
- Perform a full economic evaluation including collecting of additional data as defined in the cost consequence model.
- Consider the benefits of interviews with participants across a wider time period e.g., before and after intervention trial and with a wider variety of participants including relatives and managerial staff.

- Provide clear reporting mechanisms for safety concerns.
- Consider the strategies identified in section 5.7 to support the success of implementing a finger food menu in a different context and on a larger scale.

The next section considers how the learnings from this study has had already had more immediate impacts on clinical practice.

8.1 Reflections on clinical academic role

The PhD candidate has maintained a Clinical Doctoral Research Fellowship throughout the programme of study, working clinically as a SLT with adults in an acute hospital setting. The inspiration and motivation for undertaking this research study stemmed from the PhD candidate's interactions during her clinical role with patients in the hospital after a stroke. Many of these patients presented at risk of poor nutritional intake for multifactorial reasons and reported receiving inadequate mealtime support or were embarrassed about the mealtime support required. The PhD candidate felt that many SLT swallowing assessments do not consider eating difficulties a priority, and the hospital environment is not conducive to supporting good nutritional intake. Providing better hospital care at mealtimes and the opportunity to improve dietary intake for patients motivated the researcher to carry out this work.

The research has inspired a change in the PhD candidate’s approach to clinical work in supporting people in hospital with dysphagia and eating difficulties. Having the opportunities to diverge further into the fields of nutrition and dietetic research has fostered closer clinical working relationships with the multi-disciplinary team of hospital professions. This has prompted the PhD candidate to truly consider the impact of dysphagia on nutritional intake, satisfaction and quality of life. As a result, the PhD candidate conducts and advocates for a context-driven, holistic, evidence-based approach, considering the difficulties with swallowing as part of a patient’s mealtime difficulties, rather than in isolation. The result of this is improved patient-centred care considering not only management options for preventing the risks of aspiration but also those options which provide optimum quality of life and put nutrition at the forefront.

The PhD candidate‘s future clinical academic role will focus on encouraging hospitals to provide meals and mealtimes that fit with patients’ needs and expectations and to provide staff with the confidence and abilities to view mealtimes more than just a time-restricted task. The PhD candidate’s current clinical role supports link working between catering providers and clinical teams and educating other members of the SLT team. A current project focuses on developing a wider finger food menu with the catering team that could be tested and evaluated across wards. From a clinical point of view this study suggests that finger foods have potential benefits for use with people after stroke in hospital and therefore this intervention should be continued to be used and further data collected along the way to support evaluation.

8.1.1 Implications for health care

From a clinical perspective, it is important to consider how the findings of this feasibility study can be translated into clinical practice and shared with colleagues to influence practice. To the PhD candidate's knowledge, this is one of the first studies in the UK to evaluate the use of a finger food menu in an NHS trust, in particular for people after stroke. Maintaining a clinical role allows for immediate sharing of findings and ability to advocate for these recommendations to be a priority for clinical practice. The use of finger foods mustn't become yet another nutritional strategy for hospitals to comply with, but rather a well-evaluated approach, with practical advice on implementation within the context. Finger foods need to be used with clearer guidance and further negotiated into catering contracts to be used across wider settings. 'Postcode lottery' variation should not be a factor as to what food is provided when a patient is admitted to hospital.

The findings from this study show that dietary intake across people after stroke is variable, which supports other papers that have found similar effects. This study highlights a group of patients for whom finger foods could provide value and who are not traditionally offered finger food menus.

A valid and important concern regarding the acceptability of these types of foods is the variety of cultural influences and opinions and backgrounds present in the patient and staff populations. This study addressed participants' varied points of view using qualitative interviews. Findings suggest that patients should be offered finger food and make their own decision about whether or not they are easier to eat. This study acknowledges an important point that the provision of finger foods does not necessarily mean that a patient with cognitive and physical impairments can be fully independent at mealtimes. Staff support remains a priority and should not be dismissed and replaced with an intervention to promote independence.

Another important point for the use of this intervention in clinical practice is the requirement for a flexible approach. Despite the constraints documented in this study of regimented hospital mealtimes, participants wanted an option that could be eaten at different times of the day, dependent upon their home eating habits and familiar foods. Menus should be designed for the patients and with patient input.

This study highlights important implications for prioritising dietary intake and feeding as part of stroke rehabilitation. Hospital mealtimes need constant consideration within the changing healthcare landscape and impact of new diseases such as the COVID-19 pandemic. This pandemic has potentially altered the demographic of patients seen in hospitals and changes how mealtimes operate, e.g., with no visitors to the wards.

8.2 Final closing remarks

In closing, this study has demonstrated that it was feasible to implement and recruit patients to trial a finger food menu intervention on the study ward. There is scope for future work for the intervention to be rolled out across different contexts and to fully evaluate the patient outcomes through a randomised control trial. Careful planning is required to optimise the intervention for use on the ward and to use rigorous methodology and accurate assessment of the true impact of the intervention on patient outcomes across a longer time scale.

There is a wider need to address challenges to nutrition in hospitals with well evaluated interventions which are adequately implemented into practice to ensure sustainability.

8.3 Publications and future directions

To date, the PhD candidate has disseminated methods and results from this PhD research through one published paper and multiple conference presentations which are listed below.

Publications:

Heelan, M., Prieto, J., Roberts H., Gallant, N., Barnes, C. & Green, S. (2019) The use of finger foods in care settings: An integrative review. Journal of Human Nutrition and Dietetics.

Conference presentations:

- Oral presentation at the RCSLT dementia and mental health Clinical Excellence Network, November 2017
- Poster presentation at UK Swallow Research Group, February 2017. Abstract published: Heelan, M. (2018) Finger Foods for Older Adults in Hospital. Proceedings of UKSRG-2018. Feb 1-2, London, UK. Journal of Oral Health Dent. 2018, 1(S2):A013
- Oral presentation at Southampton Clinical Doctoral Research Fellow conference, March 2018, March 2019
- Poster presentation at Southampton Medical and Health Research Conference, June 2018
- Poster presentation at RCSLT Research Champions Conference, July 2018
- Oral presentation at Southampton Clinical Doctoral Research Fellow conference, Southampton, March 2018

- 3^{rd} place winner – Free paper oral presentation at UK Swallow Research Group, London, February 2020
- Winner – Special poster presentation at Clinical Academic Conference, March 2020
- Abstract accepted for oral presentation at European Society for Swallowing Disorders (ESSD) virtual conference, October 2020
- Abstract accepted for American Speech and Hearing Association Convention, 2020, San Diego

This PhD research provides a novel contribution to the understanding of using finger foods in hospitals for people after stroke. This addresses a gap in the current knowledge and literature base in which the PhD candidate aims to supplement with publications with the topics listed below.

Topics for proposed publications:

- A mixed methods publication discussing the methods and results from the feasibility study, detailing key recommendations for future research.
- A qualitative publication to further explore the experiences of patients and staff of using finger foods based upon the mealtime observation fieldnotes and the qualitative interviews with patients and staff.
- An opinion paper discussing the reasons for and methods to support economic evaluations of nutritional interventions.
- An opinion paper discussing methods involved in including people with aphasia to take part in research.
- A literature review exploring the existing knowledge of nutritional interventions for people with dementia and people after stroke, including an exploration as to whether interventions are suitable for both patient populations.
- Publication of dietary intake data from standard mealtimes for people in hospital after stroke.

Appendix A PRISMA checklist

Section/topic	#	Checklist item	Reported in paragraph section and on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	N/A Integrative review
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	N/A
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	Section 2.1, page 43
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	Section 2.1, page 43 and section 2.3.1, page 44
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Section 2.3.1, page 44
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	Section 2.3.2, page 45
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix B
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Section 2.3.2, page 45 and Section 2.3.3, page 46.

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	Section 2.3.3, page 46
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Section 2.3.3, page 46
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	Section 2.3.3, page 46
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	Section 2.3.4, page 47.
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Section 2.4.2, page 56.
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 2-1, page 49.
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 2-2, page 50
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Appendix D
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Synthesis for integrative review in 2.4.3, page 57.
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Section 2.4.2, page 56.
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			

Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	Section 2.5, page 60.
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	Section 2.6, page 65.
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	Section 2.5, page 60, section 2.7, page 65, section 2.8, page 67
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	Acknowledgments

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix B Database search terms

Search strategy for CINAHL Plus with Full Text (Cumulative Index of Nursing and Allied Health Literature) searched using EBSCO platform on 05/12/2020 up until December 2020.

	Search terms	**CINAHL Results**
S1	“old* person" OR "old* people" OR adult* OR patient*	2,959,918
S2	(MH "Adult")	1,176,727
S3	elder* OR senior* OR geriatric*	171,888
S4	(MH "Frail Elderly")	7,796
S5	(MH "Aged")	841,865
S6	((neuro* OR cognitive) N1 (impair* OR decline*))	38,943
S7	(MH "Dementia")	41,805
S8	dement* OR alzheimer* OR stroke	215,922
S9	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8	3,229,259
S10	"finger food*” OR fingerfood* OR buffet OR “utensil less”	541
S11	(menu* N3 modif*)	28
S12	“meal* intervention*”	64
S13	"dementia diet*"	104
S14	(eat* OR feed*) N3 (hand* OR finger*))	658
S15	((Eating OR feeding) N2 (behavio#r* OR method*))	28,306
S16	(MH "Feeding Methods")	1,789
S17	(MH "Eating Behavior")	19,359
S18	S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17	29,488
S19	S9 AND S18	14,479
S20	hospital*	567,452
S21	ward*	43,587
S22	"acute setting*"	1,287
S23	"medical setting*"	1,647
S24	((nursing OR rest OR residential* OR convalescent OR institution*) N1 (home* OR care* OR facilit*))	175,421
S25	"care home*"	5,548
S26	(MH "Hospitals")	61,828
S27	(MH "Nursing Homes")	24,617
S28	(MH "Residential Facilities")	4,794
S29	S19 AND (S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28)	309

Appendix C Grey literature search strategy

Source Name	Source Type	URL	Search terms	Date searched	Number of hits considered for inclusion
BASE (Bielefeld Academic Search Engine)	Academic search engine	https://www.base-search.net/	"Finger food"	22/05/2020	4
British Library	Catalogue of British Library collection	http://explore.bl.uk/primo_library/libweb/action/search.do?	Finger food	22/05/2020	3
Clinical trials database	Database of privately and publicly funded clinical studies conducted around the world.	https://clinicaltrials.gov/	Finger food	22/05/2020	1
EThOS	Online search of doctoral theses	https://ethos.bl.uk/SearchResuls.do	Finger food	22/05/2020	0
MedNar	Database	https://mednar.com/mednar/desktop/en/results.html	Finger food	22/05/2020	2
NDLTD	Thesis and dissertation database	http://search.ndltd.org/	Finger food	22/05/2020	0
NICE evidence search	Search for selected, authoritative evidence	https://www.evidence.nhs.uk/	Finger food	22/05/2020	12

	in health, social care and public health.				
Nuffield Trust	independent health charity, leading research - evidence base and policy	https://www.nuffieldtrust.org.uk/our-priorities	Finger food	22/05/2020	0
OAIster	open access resources	https://oaister.worldcat.org/	Finger food	22/05/2020	0
Open grey	European grey literature search engine	http://www.opengrey.eu/	Finger food	22/05/2020	0
SCIE	Largest database of information and research on all aspects of social care and social work	https://www.scie-socialcareonline.org.uk/	Finger food	22/05/2020	2
The Health Foundation	Independent health care charity search	https://www.health.org.uk/search?textsearch=finger%20food&sort_by=search_api_relevance&sort_order=DESC&page=2	Finger food	22/05/2020	0
The King's Fund	Independent healthcare charity search	https://www.kingsfund.org.uk/search?	Finger food and dementia diet	22/05/2020	0
Trip	Medical database	https://www.tripdatabase.com/	Finger food	22/05/2020	1

Appendix D CASP outcomes

CASP qualitative checklist questions	Barratt, 2001		Ford, 1996		Nangeroni, 1985	
	Outcome	Comments	Outcome	Comments	Outcome	Comments
1. Clear statement of research aims?	✓		✗	No clear research aims	✓	
2. Is a qualitative method appropriate?	✓		?	Difficult to ascertain due to limited reports of research aims	✓	
3. Appropriate research design?	✓		?	Limited study details reported	?	Limited study details reported, study design not justified.
4. Appropriate recruitment strategy?	✓		?	Limited study details reported regarding recruitment strategy.	✓	All white males aged 55-82.
5. Data collection that addressed research issue?	✓		?	Limited study details provided regarding data collection.	?	Limited study details reported regarding what data were recorded.
6. Adequate consideration of researcher and participant relationship?	?	Limited details reported, some information suggesting changes to menu based on participant information.	?	Limited study details provided.	?	Not reported.
7. Ethical issues considered?	?	Ethical considerations not fully reported, describes some concerns with randomisation and withholding potential beneficial intervention.	✗	No ethical issues considered.	✗	No ethical issues considered.
8. Sufficiently rigorous data analysis?	✓	However, no details of interrater reliability with dementia care mapping scores or details of potential researcher bias.	?	Limited study details provided.	✗	No in-depth description of analysis.
9. Clear statements of findings?	✓		✗	No clear statement of results relating back to research aims	?	Statement of findings related back to initial research aims; however, no credibility of findings discussed.
10. Valuable research?	✓		?	Implementation of the menu is fully identified; however, no areas recommendations or areas of new research are discussed.	?	Discusses contribution of study results to study population, but no recommendations or new areas of research identified.

Key: ✓ = Yes ✗ = no ? = Can't tell

Appendix D

CASP Case control checklist	Jean, 1997		Kimura, 2019		Pouyet, 2014		Soltesz, 1995		Visscher, 2020	
	Outcome	Comments	Outcome	Comments	Outcome	Comments	Outcome	Comments	Outcome	Comments
1. Clearly focused issue?	✓		✓		✓		✓		✓	
2. Appropriate method?	✓		✓		✓		✓		✓	
3. Acceptable recruitment?	✓		✓		✓		✓		✓	
4. Acceptable control group?	✓	Participants were own controls in before and after study.	✓	Participants were own controls	✓		✘	Smaller control group of people consuming modified diet	✓	Participants act as own controls
5. Accurately measured exposure?	✘	No description of validated measures and no confounding factors discussed.	?	Questionnaire completed by members of staff who were not blinded to intervention	?	Questionnaire completed by members of staff who were not blinded to intervention	✘	No details suggesting measurements were validated, no blinding of assessors described.	?	No details reported
6. Were the groups treated equally?	?	No details provided to ascertain this.	✓		✓		?		✓	
7. Potential confounding factors discussed?	✘	No discussion of confounding factors.	✓		✓		✓		?	
8. Precise results?	✘	Descriptive statistics only.	✓	No significant difference between with- and without-sauce options	✓		✓		?	
9. Believable results?	✘	High likelihood of confounding factors or chance impacting on results.	✓		✓		✓		?	
10. Results applicable to local population?	✓		?	Cultural differences with eating preferences. Only one finger food snack trialled.	✓		✓		✓	
11. Results fit with other available evidence?	✓	Follow general trend of other evidence and results.	✓		?	Only study of its kind	✓		✓	

Key: ✓ = Yes ✘ = no
? = Can't tell

CASP case control checklist questions	**Grey literature source**					
	Bailey, 2007		**Gilboy, 2019**		**Tuinier, 2014**	
	Outcome	Comments	Outcome	Comments	Outcome	Comments
1. Clearly focused issue?	✓		✓		✓	
2. Appropriate method?	✓		✓	Describes development of menu only	✓	
3. Acceptable recruitment?	✓		?	No residents recruited to trial the menu; therefore, further details could not be commented on.	✓	
4. Acceptable control group?	✓	Small sample	?	Limited details provided	?	Participants acted as own controls; however limited details provided regarding standard meal eaten
5. Accurately measured exposure?	?	Standard hospital procedure used to obtain food intake.	?		?	Unable to ascertain from limited details provided
6. Were the groups treated equally?	✓		?		?	Unable to ascertain from limited details provided
7. Potential confounding factors discussed?	✓		?		✗	No confounding factors discussed
8. Precise results?	✓		?		?	Unable to determine precise results, due to limited details provided.
9. Believable results?	?	Very small sample which does not appear to be powered likely to impact on statistical reporting of results.	?		?	
10. Results applicable to local population?	✓		?		✓	
11. Results fit with other available evidence?	✓		?		✓	Although limited other available evidence
Key: ✓ = Yes ✗ = no ? = Can't tell						

Appendix E Reflections on the researcher's insider outsider perspective

This section provides further reflections on how the position of the PhD candidate impacted this study considering the advantages and disadvantages of an insider and outsider perspective, as described by Bonner and Tolhurst (2002).

Insider perspective supporting study set up and study design

The PhD candidate's insider knowledge of the clinical setting positively supported the study setup and design. This insider knowledge meant some of the anticipated challenges associated with the study design could be accounted for within the protocol and strategies implemented to anticipate these challenges.

Naturally, the 'insider' perspective and relationships with staff favoured access to gatekeepers. The PhD candidate's clinical role included attending catering operational team meetings at the hospital site used for the research study. These were regular in-person meetings between catering managers, operational managers at the hospital Trust and Trust employees to discuss operational aspects of the catering department at the hospital site. The SLT was involved in these meetings to act as a link between the SLT team and catering team, to input into quarterly menu reviews and to advocate for the use of textured modified diets in the hospital. Prior attendance at these meetings, as part of her clinical role, meant that the researcher was well known to the catering managers and operation team. Attendance at these meetings also provided the researcher with awareness and insight into how the system for ordering food, food distribution, serving, and training for catering staff was provided within the hospital, which enhanced the development of the menu considering who needed to be involved and process to how data collection processes on the study ward. Attendance at this meeting for clinical purposes, provided the PhD candidate the opportunity to inform the catering manager and operational team about this project and to be put in contact with the catering dietitian who supported development of the menu and supported with staff training.

Being an insider, the PhD candidate was familiar with local conditions and mealtime processes on the study ward. As an SLT, the PhD candidate's clinical role meant she had previous experience of conducting assessments over mealtimes on the study ward. She was aware that paper records to record the dietary intake of patients were often not completed accurately by busy clinical staff. She noticed that the ward hosts worked under strict time constraints to deliver and clear meal trays and would be unlikely to incorporate extra demands into their job role. She noticed limited space available on the ward during mealtimes. This insider knowledge meant she knew that it would be difficult for dietary intake data collection to be the responsibility of ward staff and data collected tools needed to be conducted quickly and without taking up space on the ward. Acknowledging the time restrictions of hospital mealtimes and limited space available on the ward encouraged the PhD candidate to trial the use of digital photographs to collect dietary intake data, which could then be analysed away from the ward. This was chosen over asking staff to complete food record charts or weighing plate waste which can be timely and take up space on the study ward.

Recruiting stroke patients for the study was anticipated to be a potential challenge because people after stroke often present with stroke-associated communication difficulties, which could impact their ability to make an informed decision about participating in the study. Not directly working with patients on the ward as part of her clinical caseload and therefore being an 'outsider' meant that the PhD candidate had no prior knowledge about the potential participant's level of understanding or expressive communication difficulties. However, from an 'insider' perspective, the established links and working relationships with therapy teams meant the PhD candidate could ask clinical staff about a patient's communication deficits and be informed of the strategies to support communication. As an SLT, she understood terminology used to describe communication impairments and strategies to support participants. This knowledge meant that she could adapt the study information to an appropriate format and, where possible, could support participants to make an informed decision about participating in the study. For example, she provided paper-based communication ramps in the form of picture cards and an alphabet chart to one participant with severe dysarthria to assist them to express a decision about taking part in the study.

The PhD candidate being seen as a member of the group

Familiarity with staff members on the ward worked in favour of supporting recruitment for staff interviews. Staff were keen to support or 'help out' with the research as a good rapport existed between the PhD candidate and members of staff. However, a concern raised before the research started was that participants who were interviewed would err towards a positive spin on their experiences and views of the intervention. Being an outsider and not responsible for the participants clinical care meant that the PhD candidate's research visits were distinct to clinical contacts and roles were easily differentiated by patients. However, from an insider's perspective she was known to staff members which may have impacted how interactions took place on the ward and in interviews. Reflexivity was paramount to ensure authenticity and objectivity and reflected on throughout the data collection period and during data analysis. The PhD candidate reflected using written memos recorded after each interview. For example, the memo below reflected on a staff member needing prompting to talk about negative aspects of using finger foods on the ward.

> *Reflective memo:*
>
> *- My perceptions of persons thoughts or emotions*
>
> *HCA very relaxed during interview. Saw food as quite an emotive point of view, however similarly also considered mealtimes as a task, similar to washing or dressing. HCA appeared happy to have the opportunity to reflect on events that happened on the ward.*
>
> *- Any noticeable events during the interview.*
>
> *The interview took place in the research room and so was quiet and undisturbed. Being away from ward may have supported the HCA to feel comfortable about what she was saying. The HCA has been on the ward during many of the finger food menu trials and therefore did not feel it was necessarily look through all of the images of finger food that were available.*
>
> *Context (political, policy historical)*
>
> *The HCA was aware that I was running this project and that I have invested time into it, which is maybe why she was more positive about the foods initially than what the patients had communicated. I openly offered her the opportunity to list of problems, or challenges to using these types of food on the ward too as well as the positives. This allowed her the opportunity to talk about challenges with using finger foods, although required some prompting. It is important that in future staff interviews, staff are provided with the opportunity to give negative reflections and at the start I explain.*

The PhD candidate reflected on patients who were participants being more open about discussing negative aspects of the intervention than staff. This may have been due to the patient not knowing the PhD candidate and therefore seeing the PhD candidate as an objective observer. To enable staff to give a realistic account of their experiences of being involved in the intervention, the researcher explicitly asked staff to convey challenges or negative aspects of the intervention. Staff particularly in lower paid roles within the hospital such as health care assistants and ward hosts, enjoyed the opportunity to give their views regarding the intervention.

Familiarity in the field

Asselin (2003) notes that familiarity in the field may impede on the researcher actively noting clinical activities of interest, with being an 'insider' increasing the risk of the researcher no longer recording what they become accustomed to. Insider knowledge can act as a hindrance to the study, where knowledge is taken for granted and assumptions are made by participants that shared knowledge is understood. The PhD candidate was aware that her clinical role, concerned with safe eating on the ward, and having prior knowledge of the mealtime process meant that she could have responded to participants from a clinical perspective as opposed to a researcher. This may have meant that routine clinical tasks were missed, and focus may have attended to themes of interest. To account for this, the researcher was not working clinically on the ward during data collection, regularly noting routine clinical tasks within observations and keeping a research diary to help reflect and support the researcher to be reflexive. The PhD candidate was aware of her influences and perspectives throughout and used a high standard of reflection via memo notes, similar to the reflective approach taken in clinical practice. Reflexivity was paramount to ensure authenticity and objectivity and reflections were referred to during data analysis to support findings. For example, in section 5.6.5.5.1, page 172 a reflective memo is used as to show how the PhD candidate was required on some occasions to support with the meal preparation or prompt the catering team to present food appropriately by removing packaging.

Tensions arising when observing in the field

During the mealtime observations inner tensions within the PhD candidate's mind occurred where it was evident that clinical staff were not following what the PhD candidate would consider 'best practice'. This challenged the PhD candidate to remain in the researcher role. Ethical dilemmas were anticipated as part of undertaking lunchtime observations and outlined within the protocol and ethics forms. Despite having a clear written protocol, in practice, the researcher needed to evaluate and critically review what she was seeing on the ward and reflect on this. During mealtime observations, patients were often interrupted whilst they were eating by doctors conducting medical rounds, nursing staff giving medications and phlebotomists taking blood. As a clinician working in the hospital, the PhD candidate was aware that in theory, the hospital advocated for 'protected mealtimes', where hospital staff were requested to pause routine clinical tasks to allow patients to eat their meals without being disrupted. An example of this is shown in the field note below:

> *Phlebotomist walks in towards 007. "I've come to take some blood, but I can see you are still eating. I can come back if you want?" 007: "No you can take it now, thank you" Phlebotomist agrees and sits down next to 007. Prepares arm.*

> *Talking to phlebotomist and continues to eat sandwich with other hand. (Field note, Participant 007, Finger food meal)*

During observations, clinical staff did not appear to challenge each other for not abiding by protected mealtimes principles. Often, patients agreed to clinical interventions during mealtimes clinicians continued with care. As this was not affecting the wellbeing or safety of patients or participants, it was felt not appropriate for the researcher to intervene (Health and Care Professionals Council 2016). The PhD candidate documented these observations and discussed these reflections in clinical line management sessions.

Impact of social background of the PhD candidate

From a pragmatic viewpoint, the PhD candidate was aware that all human experience involves a level of interpretation. Inevitably the social background and personal history of the PhD candidate (a woman, in her mid-twenties, grown up in the south of England and trained as an undergraduate SLT) would impact on choices about what is important and what is appropriate and therefore the design of the study and intervention (Morgan 2007). For example, when designing the study mealtime observations were considered an acceptable approach to collect data about how the intervention was delivered. As a SLT with prior experience of working on the ward, mealtime observations were part of her clinical role and professional practice and therefore was a typical activity to undertake within the ward environment. When selecting foods to include on the finger food menu, the PhD candidates clinical background steered towards choosing foods that would be easy to eat and avoid high risk of choking.

These reflections have highlighted some of the tensions associated with the PhD candidate occupying a clinical academic role and therefore having both an insider and outsider perspective to the research. The researcher used creative ways to work with and reflect on the tensions inherent of being either an insider or outsider to the research.

Appendix F CONSORT checklist – extension for pilot and feasibility trials

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	Title
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Section 3.5, page 94
	2b	Specific objectives or research questions for pilot trial	Section 3.6.1, page 97
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Section 4.3, page 105
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Not applicable
Participants	4a	Eligibility criteria for participants	Section 4.4.1.1, page 105 and for qualitative interviews section 4.4.2.1, page 112,
	4b	Settings and locations where the data were collected	Section 4.4.1.2, page 107 and for qualitative interviews section 4.4.2.2, page 112
	4c	How participants were identified and consented	Section 4.4.1.3, page 107 and for qualitative interviews section 4.4.2.2, page 112

Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Section 4.5, page 115
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Table 3-6, page 27
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Not applicable
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Section 4.7, page 125
Sample size	7a	Rationale for numbers in the pilot trial	Section 4.4.1.5, page 111
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Not applicable
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	Not applicable
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Not applicable
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Not applicable
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Not applicable
	11b	If relevant, description of the similarity of interventions	Not applicable
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Section 3.6.1, page 97 and Section 4.10, page 126
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Section 5.2, page 140
	13b	For each group, losses and exclusions after randomisation, together with reasons	Not applicable

Recruitment	14a	Dates defining the periods of recruitment and follow-up	Section 5.3, page 141
	14b	Why the pilot trial ended or was stopped	Section 5.3, page 141
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Section 5.4, page 145
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Section 5.5, page 147
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Section 5.6, page 147
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	Findings from mealtime observations section 5.6.5, page 160157 and findings from interviews section 6.4, page 189
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Section 5.8, page 178
	19a	If relevant, other important unintended consequences	Not applicable
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Section 5.10, page 180
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Section 5.11, page 183
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Sections in Chapter 7
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Sections in Chapter 8
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	Section 4.13, page 137
Protocol	24	Where the pilot trial protocol can be accessed, if available	Not applicable
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Acknowledgments
	26	Ethical approval or approval by research review committee, confirmed with reference number	Section 4.13, page 137

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.
*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix G Study designs considered

Study design option	Methods	Advantages	Disadvantages
1. Cluster randomised control trial	• Single ward, Cluster randomisation by bay (up to 6 participants in each bay) • 1 bay control group – standard menu • 1 bay intervention group – finger food menu	• Cluster randomisation provides logistical convenience and reduces the requirement for randomised sampling of individual participants. • Administratively, conducting the randomisation sequence for this method is more convenient (Walker 2014). • This method would allow for a control group to be used.	• Due to only one ward being used, cluster randomisation is unable to be conducted at ward level. Close proximity of cluster groups between bays will increase risk of contamination, e.g., staff may be working in both intervention and control groups within the same shift. • Power and precision of trial will be lower than individual randomised control trial. • Due to clinical demands, the researcher may have limited control on the movement of participants between bays and therefore movement between cluster groups. • Bays within the ward are separated by gender and staff support required, therefore variation within cluster groups will exist. • Not all patients will be suitable for finger foods in the same bay, which puts pressure on recruitment.
2. Cross over trial	• Single ward • Cross over at patient level – randomised to whether	• Participants act as own control, making the design less susceptible to confounders. • Within participant variability likely to be less than between participant variability.	• In a cross over trial there needs to be an adequate washout period to limit carry over effect.

Study design option	Methods	Advantages	Disadvantages
	having finger food or standard menu first	More precise comparisons between treatment options can be made and therefore a smaller sample size can be used (Walker 2014). • Participants can be recruited from any bay on the ward, increasing the pool of potentially eligible participants.	• Appropriate wash out time would mean that the trial length is increased, increasing risk of attrition. • Difficult to predict appropriate wash out time. • Participants may drop out after the first treatment (Walker 2014).
3. ‘Before and after’/pre-post study design	• Outcomes compared before and after the finger food menu is provided. Baseline measure taken and then repeated after individuals have trialled the intervention.	• The limited resources and manpower required for this study design will support study success. • Participants can be recruited from any bay on the ward, increasing the pool of potentially eligible participants. • This design is a cost-effective preliminary study which can be used to decide whether future research should be conducted (Frey 2018).	• No control or comparison group used which limits validity of the design. • Unable to show a causal change between independent and dependent variables due to high threat of internal validity (Frey 2018).
4. Randomised control trial at patient level.	• Patients randomised to standard menu or finger food menu on consent to study.	• Gold standard trial methodology where causal relationships could be made between standard care and implementation of finger food menu. • The risk of extraneous and confounding variables is minimised. • Control over the introduction and variation of the predictor variables clarifies the direction of the cause and effect.	• Poor randomisation can introduce bias, e.g., randomising participants using simple randomisation with a small sample size poses a risk of imbalanced demographic variables (Walker 2014). • Blinding of researcher and participants is limited and therefore may introduce bias. Participants will be aware which menu they are ordering from and a single, lone researcher is conducting the study, which limits ability to blind the researcher.

Study design option	Methods	Advantages	Disadvantages
		• Pre and post testing controls for time related threats. • Participants can be recruited from any bay on the ward, increasing the pool of potentially eligible participants.	• Ethical limitations to randomisation meant that this study design may be less acceptable to potential participants and impact recruitment. • Staff working with participants on both intervention and control group may risk contamination. • Challenges with the feasibility of randomisation at patient level on a clinical ward implementing a new hospital menu have been previously documented (Collins et al. 2017b)

Appendix H Ward information poster

NHS
University Hospital Southampton
NHS Foundation Trust

UNIVERSITY OF
Southampton

RESEARCH IS HAPPENING ON THIS WARD

Your friend or relative may be asked to participate in a research study.

It includes trialling foods that can be eaten with the hands and without cutlery.

Why are we doing this study?

We are doing this study to look at what people think about using these types of food in hospital. We hope to find out information to help us improve patient experience of hospital mealtimes in the future.

For more information

Contact the researcher: Milly Heelan

A.r.heelan@soton.ac.uk | Phone: 02381 203919

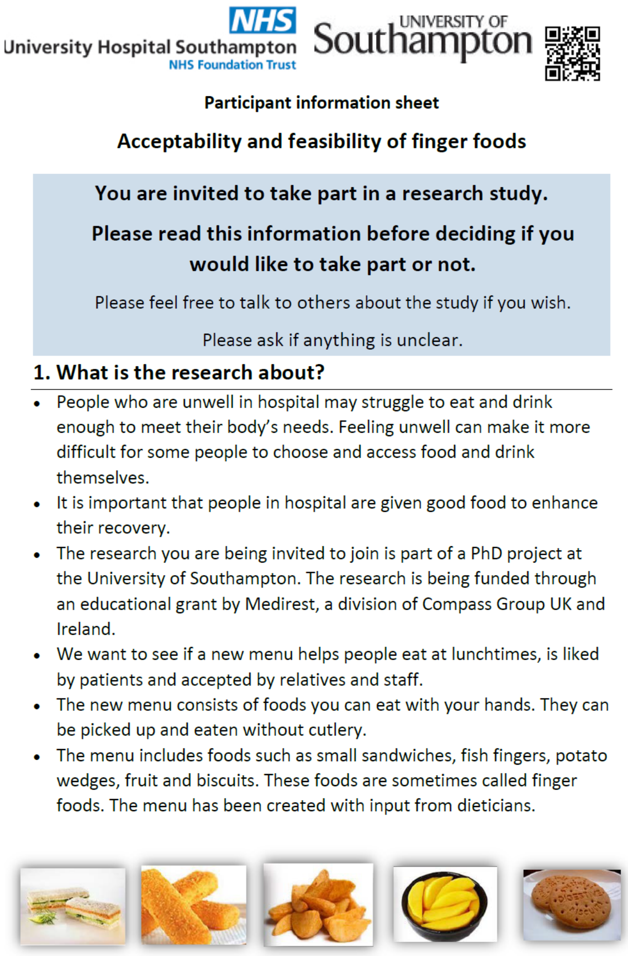
If you, your friend or relative **would not** like to be approached for this research project, please contact the ward manager:

ERGO: 40715 IRAS: 240341
02/10/2018

Take down date:

Ward poster 0.2

Appendix I Participant information sheet



University Hospital Southampton NHS Foundation Trust

UNIVERSITY OF Southampton

Participant information sheet

Acceptability and feasibility of finger foods

You are invited to take part in a research study.

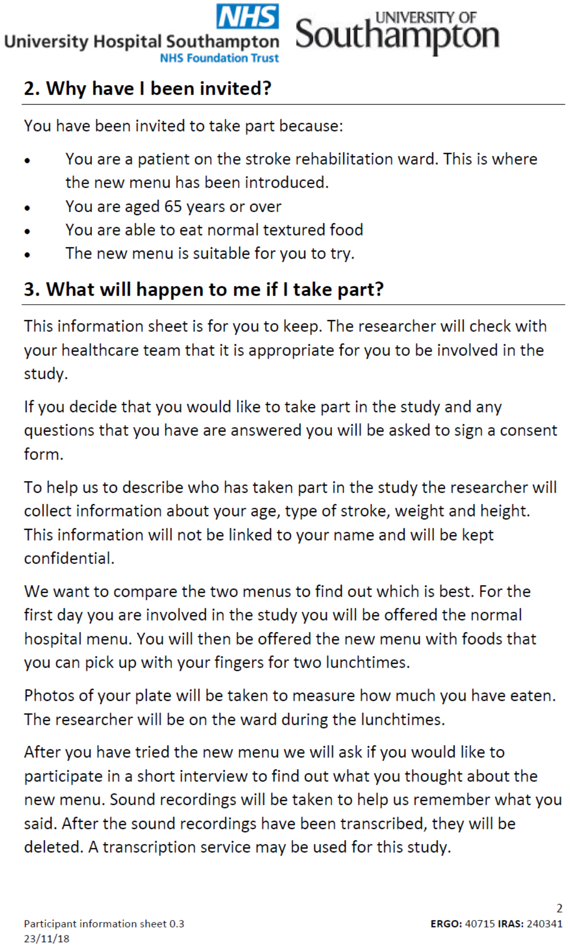
Please read this information before deciding if you would like to take part or not.

Please feel free to talk to others about the study if you wish.

Please ask if anything is unclear.

1. What is the research about?

- People who are unwell in hospital may struggle to eat and drink enough to meet their body's needs. Feeling unwell can make it more difficult for some people to choose and access food and drink themselves.
- It is important that people in hospital are given good food to enhance their recovery.
- The research you are being invited to join is part of a PhD project at the University of Southampton. The research is being funded through an educational grant by Medirest, a division of Compass Group UK and Ireland.
- We want to see if a new menu helps people eat at lunchtimes, is liked by patients and accepted by relatives and staff.
- The new menu consists of foods you can eat with your hands. They can be picked up and eaten without cutlery.
- The menu includes foods such as small sandwiches, fish fingers, potato wedges, fruit and biscuits. These foods are sometimes called finger foods. The menu has been created with input from dieticians.



University Hospital Southampton NHS Foundation Trust

UNIVERSITY OF Southampton

2. Why have I been invited?

You have been invited to take part because:

- You are a patient on the stroke rehabilitation ward. This is where the new menu has been introduced.
- You are aged 65 years or over
- You are able to eat normal textured food
- The new menu is suitable for you to try.

3. What will happen to me if I take part?

This information sheet is for you to keep. The researcher will check with your healthcare team that it is appropriate for you to be involved in the study.

If you decide that you would like to take part in the study and any questions that you have are answered you will be asked to sign a consent form.

To help us to describe who has taken part in the study the researcher will collect information about your age, type of stroke, weight and height. This information will not be linked to your name and will be kept confidential.

We want to compare the two menus to find out which is best. For the first day you are involved in the study you will be offered the normal hospital menu. You will then be offered the new menu with foods that you can pick up with your fingers for two lunchtimes.

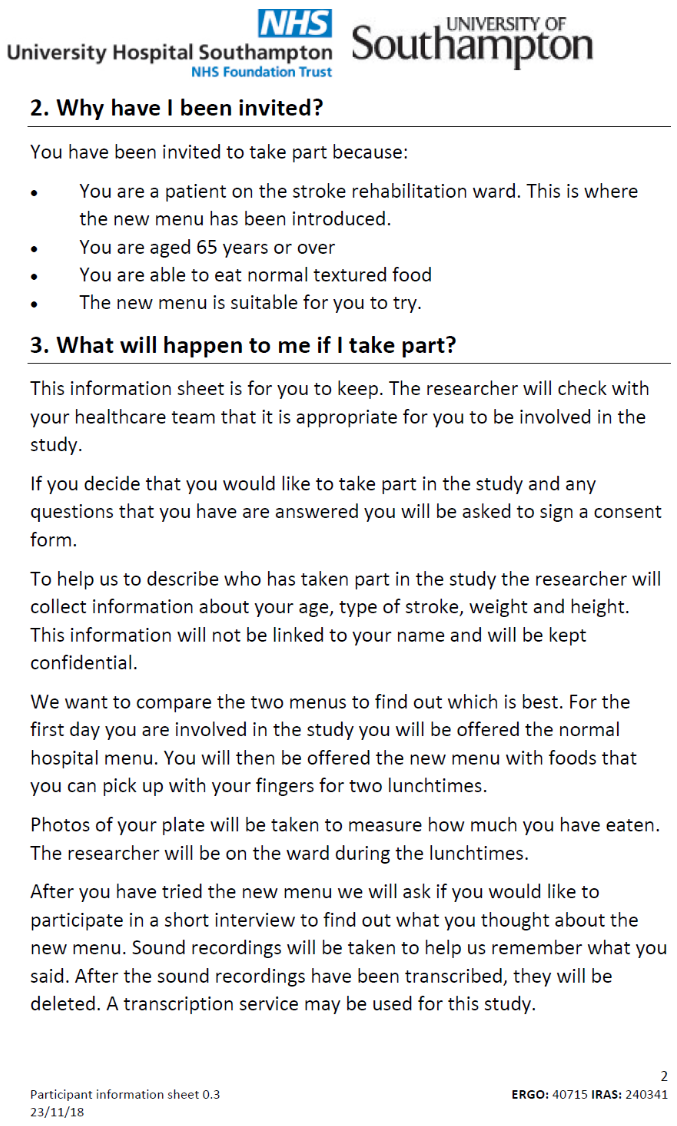
Photos of your plate will be taken to measure how much you have eaten. The researcher will be on the ward during the lunchtimes.

After you have tried the new menu we will ask if you would like to participate in a short interview to find out what you thought about the new menu. Sound recordings will be taken to help us remember what you said. After the sound recordings have been transcribed, they will be deleted. A transcription service may be used for this study.

2

Participant information sheet 0.3
23/11/18

ERGO: 40715 **IRAS:** 240341



2. Why have I been invited?

You have been invited to take part because:

- You are a patient on the stroke rehabilitation ward. This is where the new menu has been introduced.
- You are aged 65 years or over
- You are able to eat normal textured food
- The new menu is suitable for you to try.

3. What will happen to me if I take part?

This information sheet is for you to keep. The researcher will check with your healthcare team that it is appropriate for you to be involved in the study.

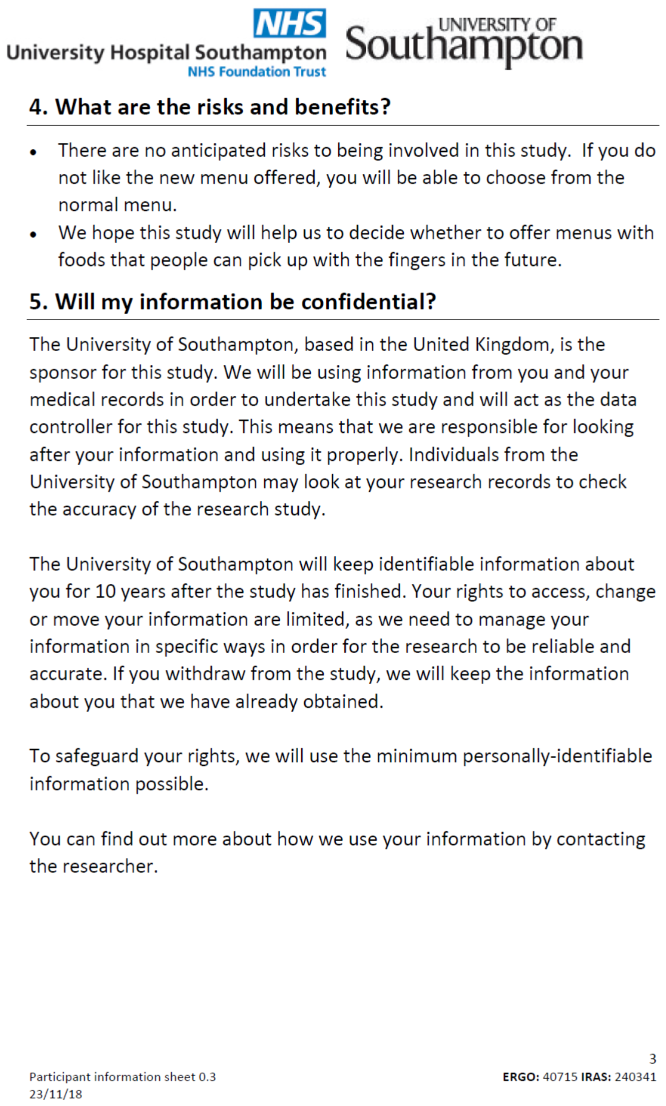
If you decide that you would like to take part in the study and any questions that you have are answered you will be asked to sign a consent form.

To help us to describe who has taken part in the study the researcher will collect information about your age, type of stroke, weight and height. This information will not be linked to your name and will be kept confidential.

We want to compare the two menus to find out which is best. For the first day you are involved in the study you will be offered the normal hospital menu. You will then be offered the new menu with foods that you can pick up with your fingers for two lunchtimes.

Photos of your plate will be taken to measure how much you have eaten. The researcher will be on the ward during the lunchtimes.

After you have tried the new menu we will ask if you would like to participate in a short interview to find out what you thought about the new menu. Sound recordings will be taken to help us remember what you said. After the sound recordings have been transcribed, they will be deleted. A transcription service may be used for this study.



4. What are the risks and benefits?

- There are no anticipated risks to being involved in this study. If you do not like the new menu offered, you will be able to choose from the normal menu.
- We hope this study will help us to decide whether to offer menus with foods that people can pick up with the fingers in the future.

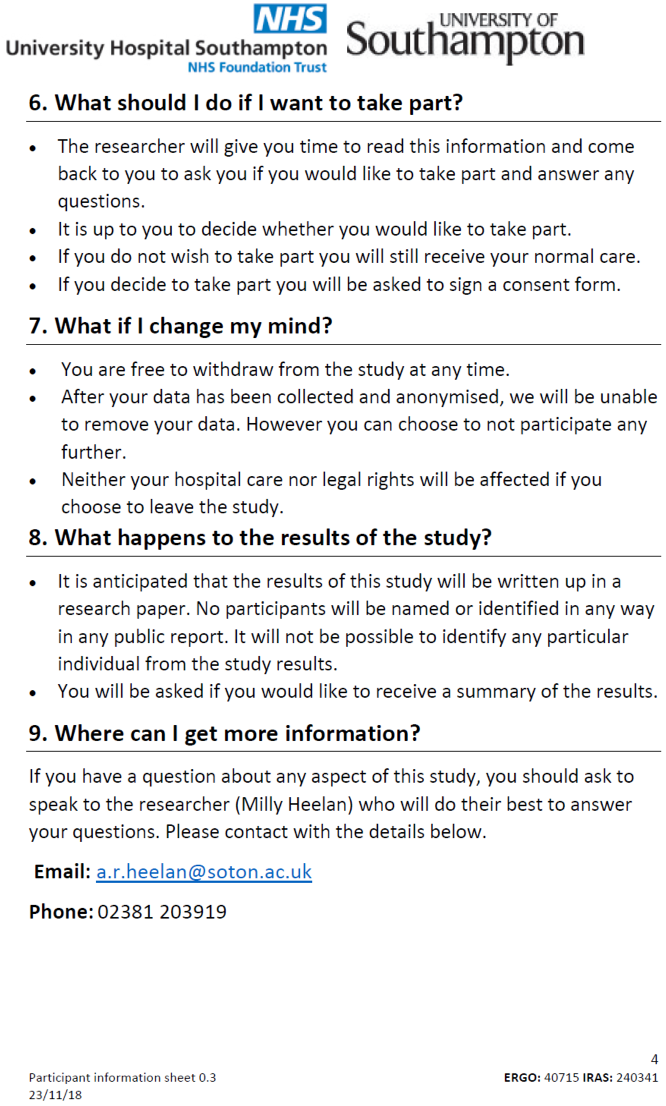
5. Will my information be confidential?

The University of Southampton, based in the United Kingdom, is the sponsor for this study. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Individuals from the University of Southampton may look at your research records to check the accuracy of the research study.

The University of Southampton will keep identifiable information about you for 10 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.

To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the researcher.



6. What should I do if I want to take part?

- The researcher will give you time to read this information and come back to you to ask you if you would like to take part and answer any questions.
- It is up to you to decide whether you would like to take part.
- If you do not wish to take part you will still receive your normal care.
- If you decide to take part you will be asked to sign a consent form.

7. What if I change my mind?

- You are free to withdraw from the study at any time.
- After your data has been collected and anonymised, we will be unable to remove your data. However you can choose to not participate any further.
- Neither your hospital care nor legal rights will be affected if you choose to leave the study.

8. What happens to the results of the study?

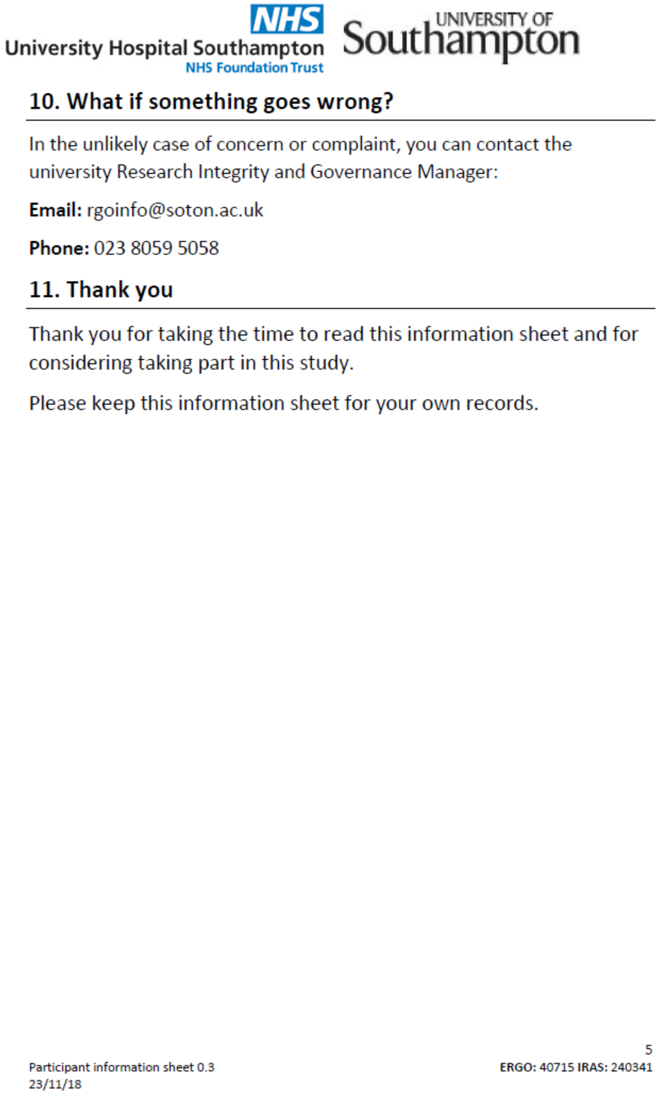
- It is anticipated that the results of this study will be written up in a research paper. No participants will be named or identified in any way in any public report. It will not be possible to identify any particular individual from the study results.
- You will be asked if you would like to receive a summary of the results.

9. Where can I get more information?

If you have a question about any aspect of this study, you should ask to speak to the researcher (Milly Heelan) who will do their best to answer your questions. Please contact with the details below.

Email: a.r.heelan@soton.ac.uk

Phone: 02381 203919



10. What if something goes wrong?

In the unlikely case of concern or complaint, you can contact the university Research Integrity and Governance Manager:

Email: rgoinfo@soton.ac.uk

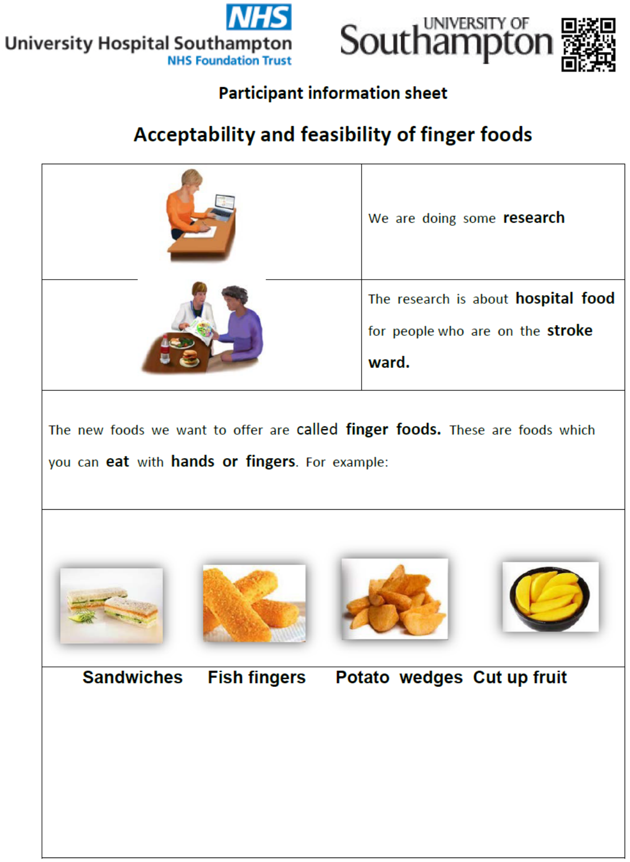
Phone: 023 8059 5058

11. Thank you

Thank you for taking the time to read this information sheet and for considering taking part in this study.

Please keep this information sheet for your own records.

Appendix J Aphasia friendly participant information sheet



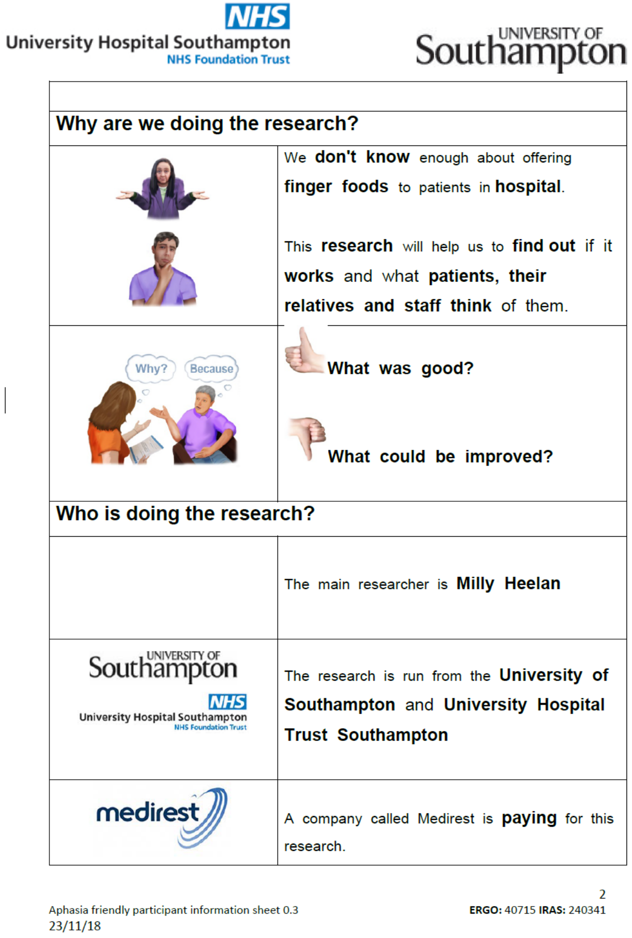
Participant information sheet

Acceptability and feasibility of finger foods

	We are doing some **research**
	The research is about **hospital food** for people who are on the **stroke ward.**

The new foods we want to offer are called **finger foods.** These are foods which you can **eat** with **hands or fingers**. For example:

Sandwiches	**Fish fingers**	**Potato wedges**	**Cut up fruit**

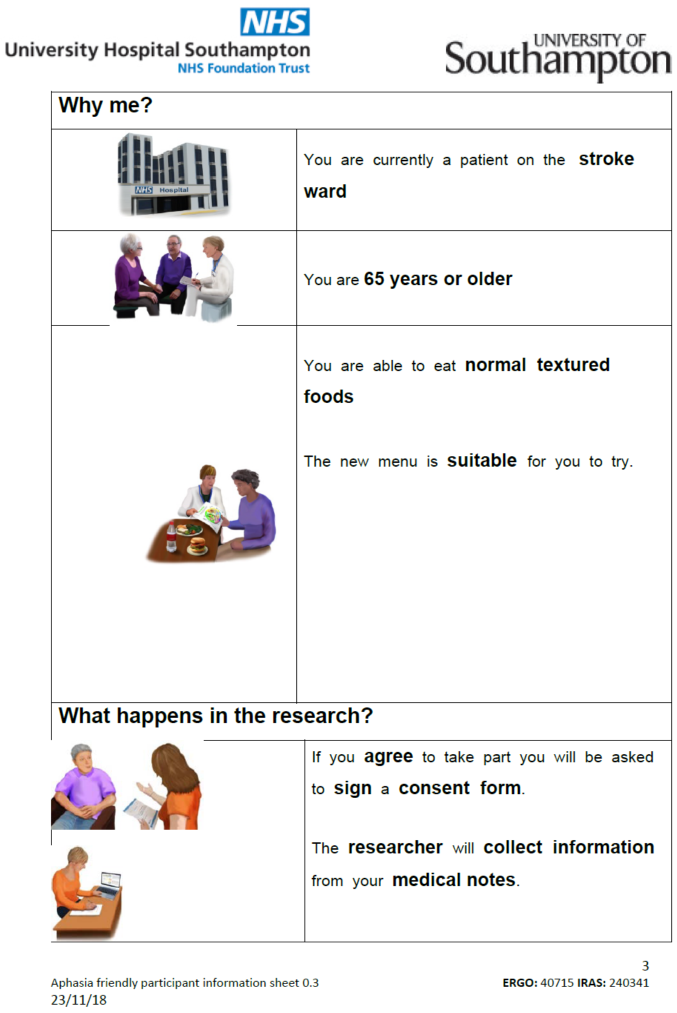


Why are we doing the research?	
	We **don't know** enough about offering **finger foods** to patients in **hospital**. This **research** will help us to **find out** if it **works** and what **patients, their relatives and staff think** of them.
	What was good? **What could be improved?**
Who is doing the research?	
	The main researcher is **Milly Heelan**
	The research is run from the **University of Southampton** and **University Hospital Trust Southampton**
	A company called Medirest is **paying** for this research.

2

Aphasia friendly participant information sheet 0.3
23/11/18

ERGO: 40715 **IRAS:** 240341



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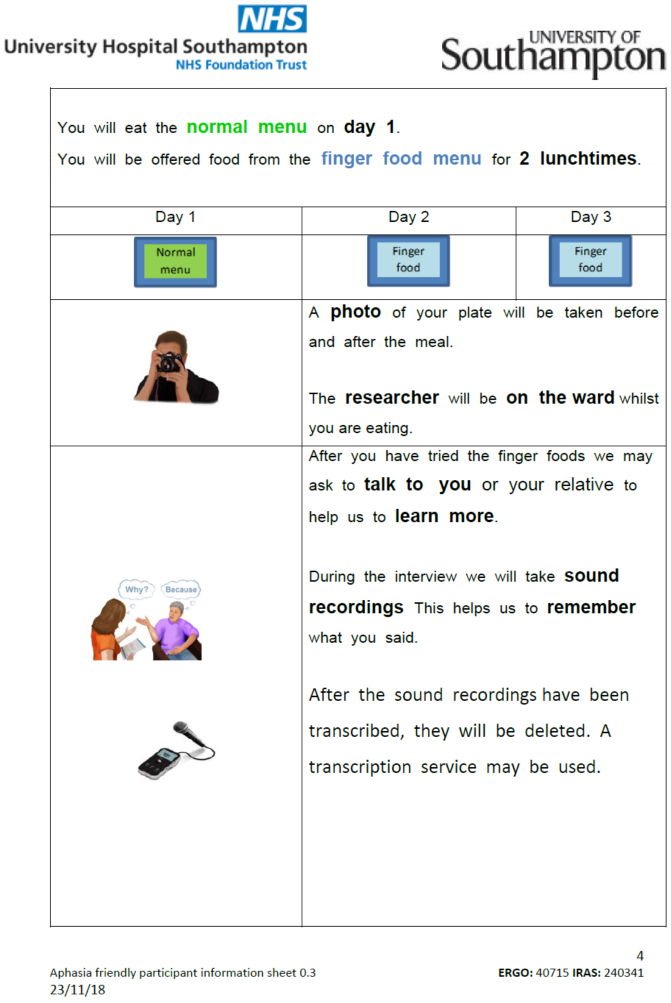
Why me?	
	You are currently a patient on the **stroke ward**
	You are **65 years or older**
	You are able to eat **normal textured foods** The new menu is **suitable** for you to try.

What happens in the research?	
	If you **agree** to take part you will be asked to **sign** a **consent form**. The **researcher** will **collect information** from your **medical notes**.

3

Aphasia friendly participant information sheet 0.3 23/11/18

ERGO: 40715 **IRAS:** 240341



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You will eat the **normal menu** on **day 1**.

You will be offered food from the **finger food menu** for **2 lunchtimes**.

Day 1	Day 2	Day 3
Normal menu	Finger food	Finger food

	A **photo** of your plate will be taken before and after the meal. The **researcher** will be **on the ward** whilst you are eating.
	After you have tried the finger foods we may ask to **talk to you** or your relative to help us to **learn more**. During the interview we will take **sound recordings** This helps us to **remember** what you said. After the sound recordings have been transcribed, they will be deleted. A transcription service may be used.

4

Aphasia friendly participant information sheet 0.3 23/11/18

ERGO: 40715 **IRAS:** 240341

What might be good about taking part?

	You may **enjoy** taking part
	You may find it **interesting**
	We **don't think** there any **risks** to taking part. If you don't like the new foods we can offer you foods from the normal menu.

Who will see the information about me?

	We will keep the **information** about you **safe** Your research records may be **checked** by people from the University of Southampton.

	We will **tell your doctor** that you are in this research project

What if I want to take part in the research?

	If you decide to take part you will need to **sign a consent form** This says that **you understand** the research and **you agree** to take part
 	You may want **more information** Contact **the researcher** She will **answer your questions** Milly Heelan Email: a.r.heelan@soton.ac.uk Phone: 02381 203919

What if I don't take part in the research?

	You will still get your **normal help.**

What will happen after the research?

	If you agree we will **give you the results** of the research

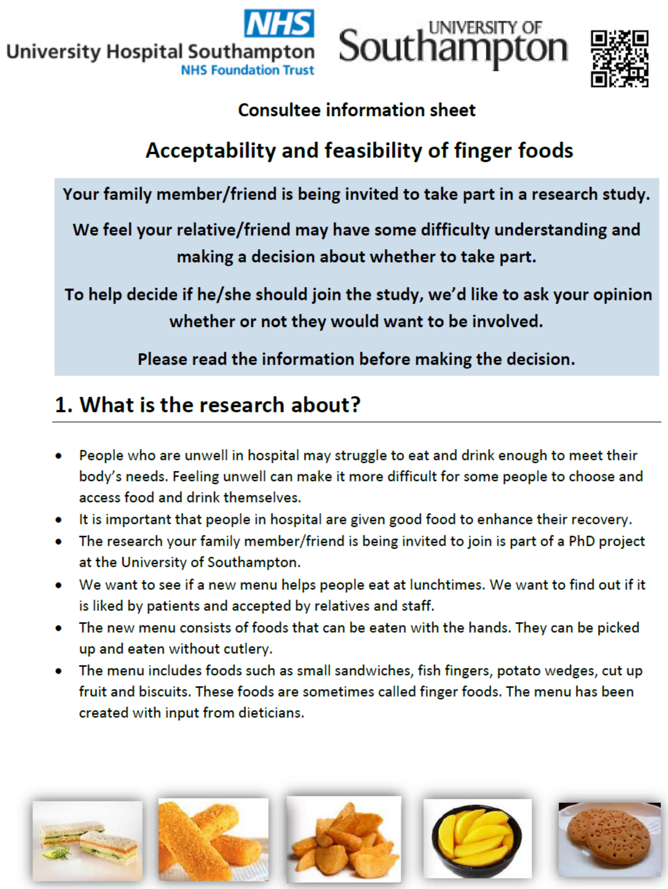
	We will share the **results** with **other researchers** at **conferences** and in **academic journals**
	The results will **not use your name**
	The results may include **what you said** but **not who said it**

What if something goes wrong?

  	This is very **unlikely** But if you have **worries** about the research, please contact: *Research Integrity and Governance Manager* *023 8059 5058* *rgoinfo@soton.ac.uk*

	The University has **insurance**

Appendix K Consultee information sheet



University Hospital Southampton NHS Foundation Trust

UNIVERSITY OF Southampton

Consultee information sheet

Acceptability and feasibility of finger foods

Your family member/friend is being invited to take part in a research study.

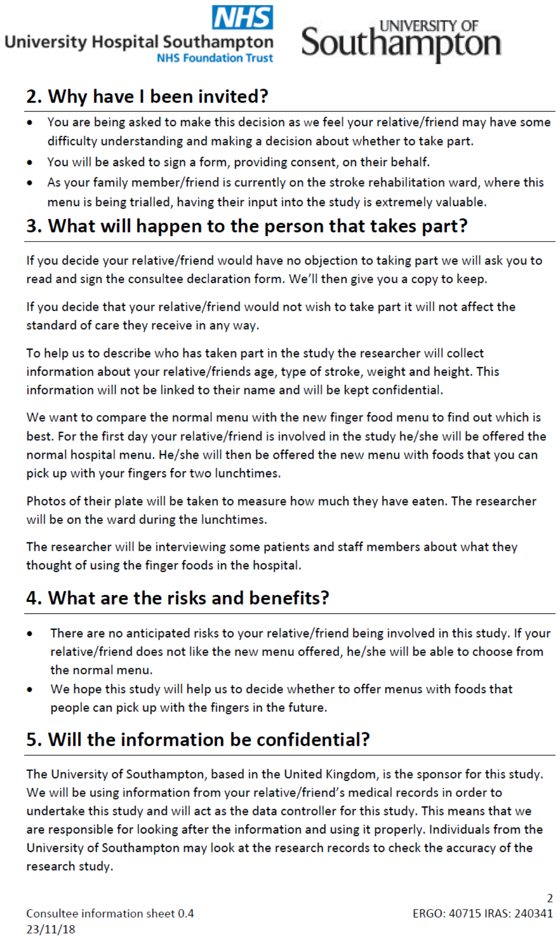
We feel your relative/friend may have some difficulty understanding and making a decision about whether to take part.

To help decide if he/she should join the study, we'd like to ask your opinion whether or not they would want to be involved.

Please read the information before making the decision.

1. What is the research about?

- People who are unwell in hospital may struggle to eat and drink enough to meet their body's needs. Feeling unwell can make it more difficult for some people to choose and access food and drink themselves.
- It is important that people in hospital are given good food to enhance their recovery.
- The research your family member/friend is being invited to join is part of a PhD project at the University of Southampton.
- We want to see if a new menu helps people eat at lunchtimes. We want to find out if it is liked by patients and accepted by relatives and staff.
- The new menu consists of foods that can be eaten with the hands. They can be picked up and eaten without cutlery.
- The menu includes foods such as small sandwiches, fish fingers, potato wedges, cut up fruit and biscuits. These foods are sometimes called finger foods. The menu has been created with input from dieticians.



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2. Why have I been invited?

- You are being asked to make this decision as we feel your relative/friend may have some difficulty understanding and making a decision about whether to take part.
- You will be asked to sign a form, providing consent, on their behalf.
- As your family member/friend is currently on the stroke rehabilitation ward, where this menu is being trialled, having their input into the study is extremely valuable.

3. What will happen to the person that takes part?

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration form. We'll then give you a copy to keep.

If you decide that your relative/friend would not wish to take part it will not affect the standard of care they receive in any way.

To help us to describe who has taken part in the study the researcher will collect information about your relative/friends age, type of stroke, weight and height. This information will not be linked to their name and will be kept confidential.

We want to compare the normal menu with the new finger food menu to find out which is best. For the first day your relative/friend is involved in the study he/she will be offered the normal hospital menu. He/she will then be offered the new menu with foods that you can pick up with your fingers for two lunchtimes.

Photos of their plate will be taken to measure how much they have eaten. The researcher will be on the ward during the lunchtimes.

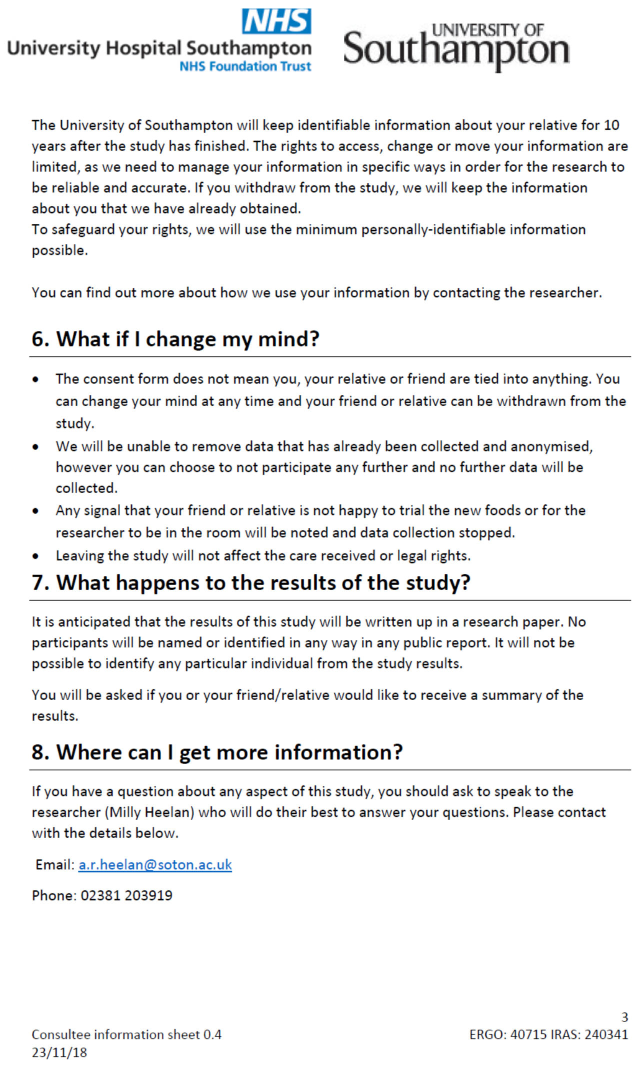
The researcher will be interviewing some patients and staff members about what they thought of using the finger foods in the hospital.

4. What are the risks and benefits?

- There are no anticipated risks to your relative/friend being involved in this study. If your relative/friend does not like the new menu offered, he/she will be able to choose from the normal menu.
- We hope this study will help us to decide whether to offer menus with foods that people can pick up with the fingers in the future.

5. Will the information be confidential?

The University of Southampton, based in the United Kingdom, is the sponsor for this study. We will be using information from your relative/friend's medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after the information and using it properly. Individuals from the University of Southampton may look at the research records to check the accuracy of the research study.



The University of Southampton will keep identifiable information about your relative for 10 years after the study has finished. The rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.
To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting the researcher.

6. What if I change my mind?

- The consent form does not mean you, your relative or friend are tied into anything. You can change your mind at any time and your friend or relative can be withdrawn from the study.
- We will be unable to remove data that has already been collected and anonymised, however you can choose to not participate any further and no further data will be collected.
- Any signal that your friend or relative is not happy to trial the new foods or for the researcher to be in the room will be noted and data collection stopped.
- Leaving the study will not affect the care received or legal rights.

7. What happens to the results of the study?

It is anticipated that the results of this study will be written up in a research paper. No participants will be named or identified in any way in any public report. It will not be possible to identify any particular individual from the study results.

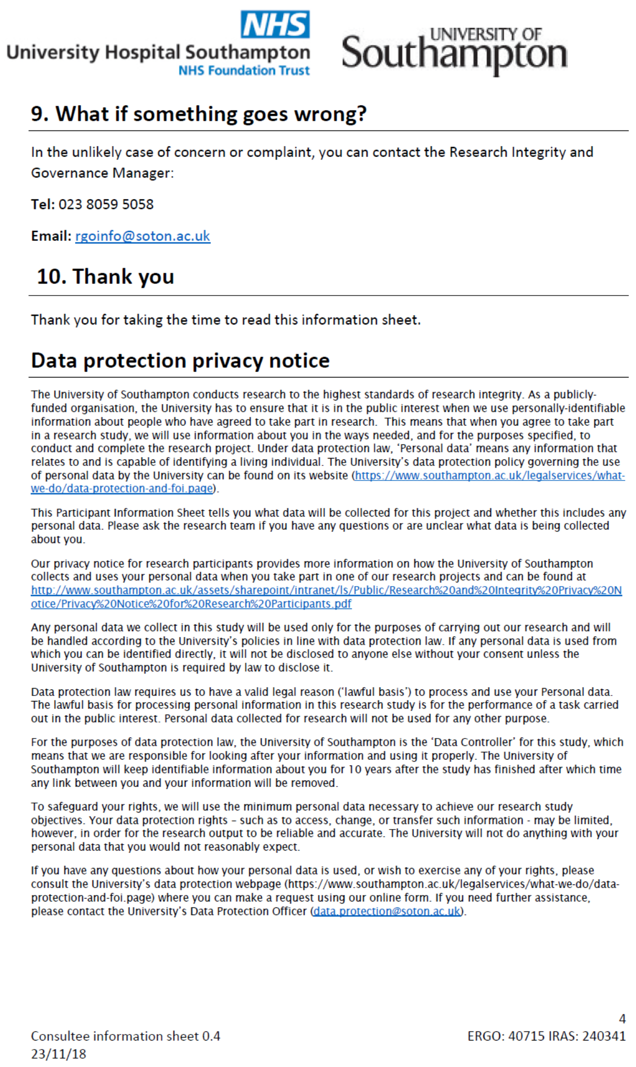
You will be asked if you or your friend/relative would like to receive a summary of the results.

8. Where can I get more information?

If you have a question about any aspect of this study, you should ask to speak to the researcher (Milly Heelan) who will do their best to answer your questions. Please contact with the details below.

Email: a.r.heelan@soton.ac.uk

Phone: 02381 203919



9. What if something goes wrong?

In the unlikely case of concern or complaint, you can contact the Research Integrity and Governance Manager:

Tel: 023 8059 5058

Email: rgoinfo@soton.ac.uk

10. Thank you

Thank you for taking the time to read this information sheet.

Data protection privacy notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Appendix L Staff interview recruitment poster

NHS
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Are you a member of staff involved with mealtimes?
Are you interested in taking part in a short interview?

We have been trialling a finger food menu on this ward. We want to get staff views on what they thought about the new menu.

Interviews will take place at SGH. You will be given a £20 voucher to reimburse you for your time.

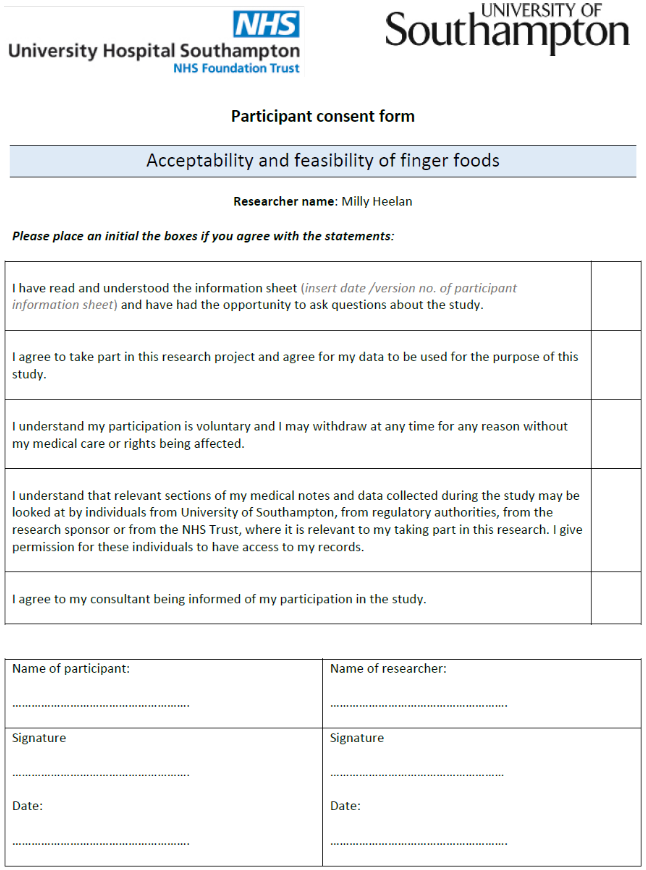
For more information or to take part:
Contact the researcher Milly Heelan
A.r.heelan@soton.ac.uk
Phone: 02381 203919

Interview poster 0.2
02/10/2018

Take down date:

ERGO: 40715 IRAS: 240341

Appendix M Patient consent form



University Hospital Southampton
NHS Foundation Trust

UNIVERSITY OF Southampton

Participant consent form

Acceptability and feasibility of finger foods

Researcher name: Milly Heelan

Please place an initial the boxes if you agree with the statements:

I have read and understood the information sheet (*insert date /version no. of participant information sheet*) and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw at any time for any reason without my medical care or rights being affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Southampton, from regulatory authorities, from the research sponsor or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I agree to my consultant being informed of my participation in the study.	

Name of participant: …………………………………………	Name of researcher: …………………………………………
Signature ………………………………………… Date: …………………………………………	Signature ………………………………………… Date: …………………………………………

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NHS Foundation Trust

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Optional - please only initial the boxes you wish to agree to:

I agree to consider doing short interview about my experience of taking part in the study.	
I understand that my interview will be audio recorded.	

Name of participant: …………………………………………	Name of researcher: …………………………………………
Signature ………………………………………… Date: …………………………………………	Signature ………………………………………… Date: …………………………………………

Appendix N Staff participant information sheet

University Hospital Southampton NHS Foundation Trust

University of Southampton

Staff participant information sheet

Acceptability and feasibility of finger foods

You are invited to take part in an interview for a research study.

Please read this information before deciding if you would like to take part or not.

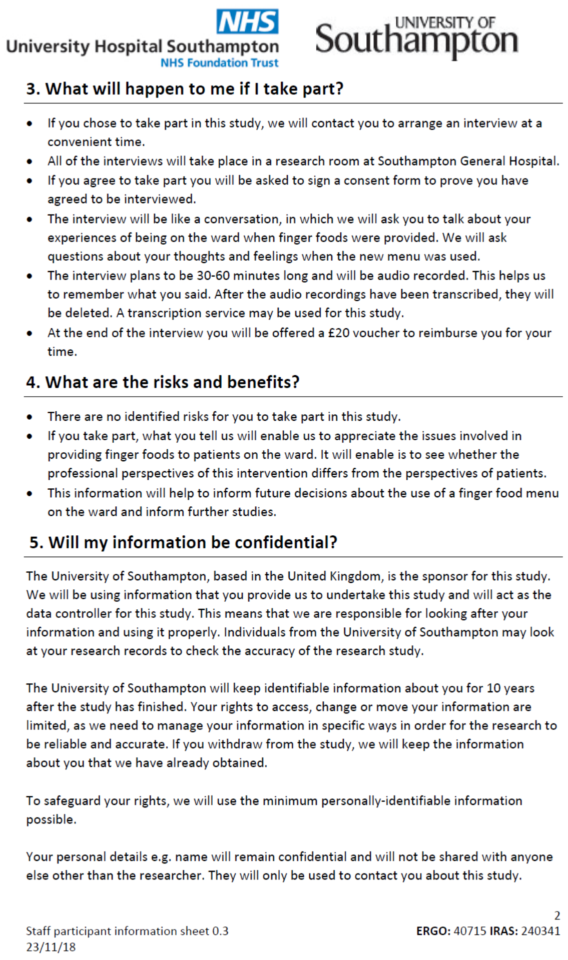
Please ask if anything is unclear.

1. What is the research about?

- People who are unwell in hospital may struggle to eat and drink enough to meet their body's needs. It can be difficult for some people after stroke to access food and drink themselves.
- The research you are being invited to join is part of a PhD project at the University of Southampton. The research is being funded through an educational grant by Medirest, a division of Compass Group UK and Ireland.
- We have been using a new menu that consists of foods you can eat with your hands or fingers for patients on the F8 stroke ward. We want to find out what staff thought about using this menu.
- We are asking staff that work on the F8 stroke ward at lunchtimes to participate in an interview. In the interview we will ask questions about your experience of working with patients who have eaten the finger foods. We will ask you to discuss the facilitators and barriers to using these types of food in hospital. This will help us to understand what worked well or not so well.
- This aims to inform important factors for using these types of food in hospital in the future.

2. Why have I been invited?

You have been invited because you are a member of staff that supports mealtimes the stroke rehabilitation ward. Your insight into what happens at meal times will be valuable to the overall findings of the study.



University Hospital Southampton NHS Foundation Trust

University of Southampton

3. What will happen to me if I take part?

- If you chose to take part in this study, we will contact you to arrange an interview at a convenient time.
- All of the interviews will take place in a research room at Southampton General Hospital.
- If you agree to take part you will be asked to sign a consent form to prove you have agreed to be interviewed.
- The interview will be like a conversation, in which we will ask you to talk about your experiences of being on the ward when finger foods were provided. We will ask questions about your thoughts and feelings when the new menu was used.
- The interview plans to be 30-60 minutes long and will be audio recorded. This helps us to remember what you said. After the audio recordings have been transcribed, they will be deleted. A transcription service may be used for this study.
- At the end of the interview you will be offered a £20 voucher to reimburse you for your time.

4. What are the risks and benefits?

- There are no identified risks for you to take part in this study.
- If you take part, what you tell us will enable us to appreciate the issues involved in providing finger foods to patients on the ward. It will enable is to see whether the professional perspectives of this intervention differs from the perspectives of patients.
- This information will help to inform future decisions about the use of a finger food menu on the ward and inform further studies.

5. Will my information be confidential?

The University of Southampton, based in the United Kingdom, is the sponsor for this study. We will be using information that you provide us to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Individuals from the University of Southampton may look at your research records to check the accuracy of the research study.

The University of Southampton will keep identifiable information about you for 10 years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.

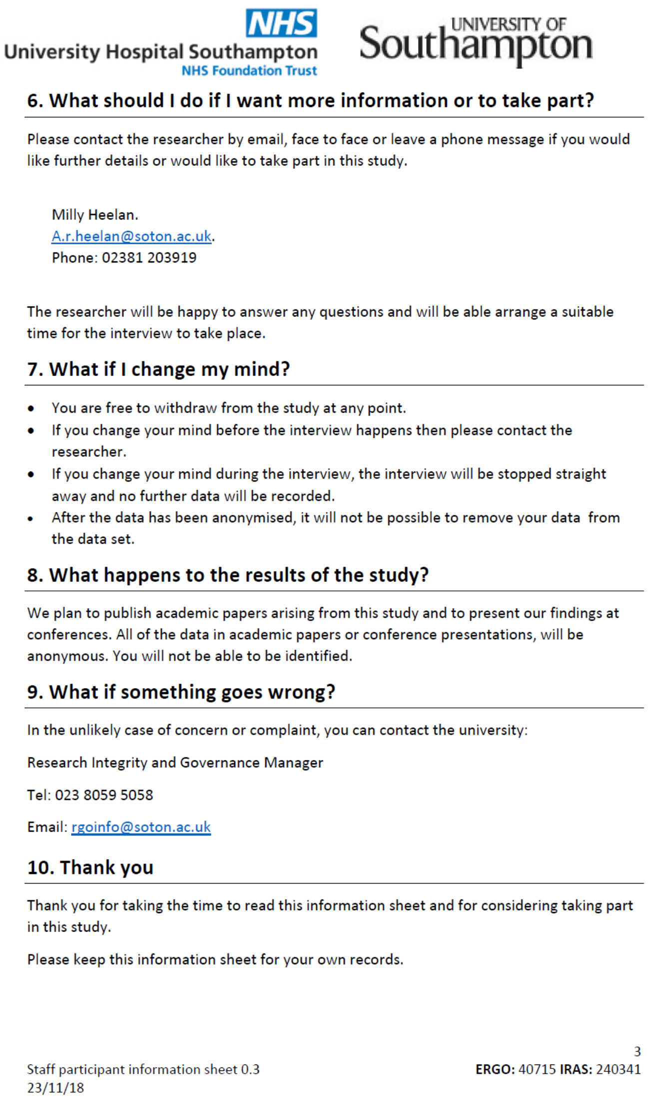
To safeguard your rights, we will use the minimum personally-identifiable information possible.

Your personal details e.g. name will remain confidential and will not be shared with anyone else other than the researcher. They will only be used to contact you about this study.

2

Staff participant information sheet 0.3
23/11/18

ERGO: 40715 **IRAS:** 240341



University Hospital Southampton NHS Foundation Trust

UNIVERSITY OF Southampton

6. What should I do if I want more information or to take part?

Please contact the researcher by email, face to face or leave a phone message if you would like further details or would like to take part in this study.

Milly Heelan.
A.r.heelan@soton.ac.uk.
Phone: 02381 203919

The researcher will be happy to answer any questions and will be able arrange a suitable time for the interview to take place.

7. What if I change my mind?

- You are free to withdraw from the study at any point.
- If you change your mind before the interview happens then please contact the researcher.
- If you change your mind during the interview, the interview will be stopped straight away and no further data will be recorded.
- After the data has been anonymised, it will not be possible to remove your data from the data set.

8. What happens to the results of the study?

We plan to publish academic papers arising from this study and to present our findings at conferences. All of the data in academic papers or conference presentations, will be anonymous. You will not be able to be identified.

9. What if something goes wrong?

In the unlikely case of concern or complaint, you can contact the university:

Research Integrity and Governance Manager

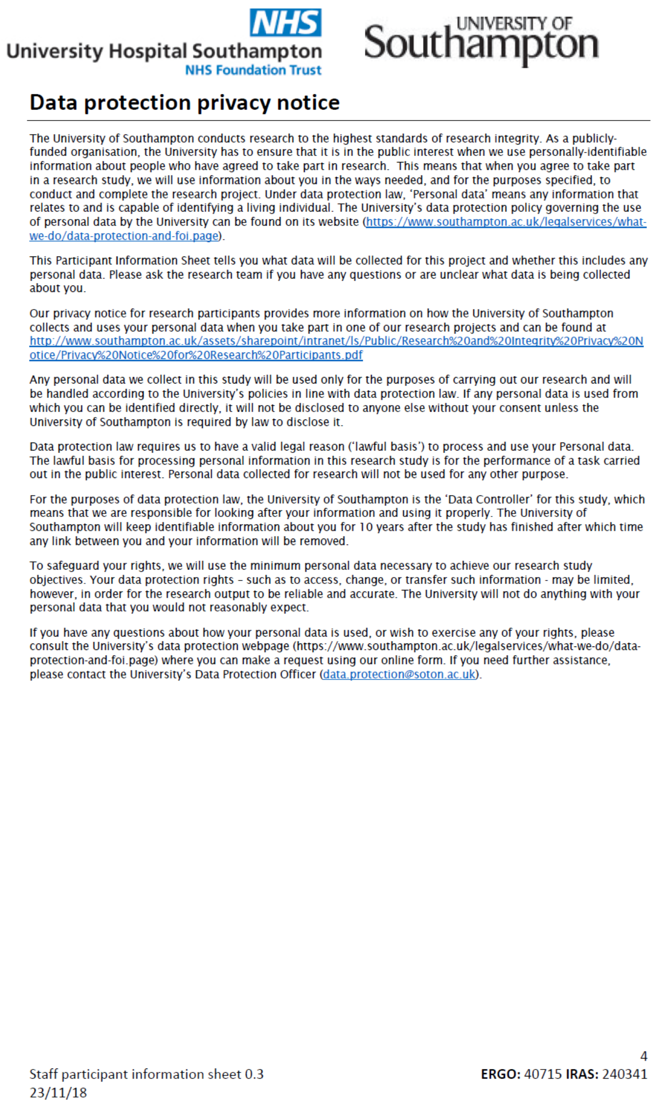
Tel: 023 8059 5058

Email: rgoinfo@soton.ac.uk

10. Thank you

Thank you for taking the time to read this information sheet and for considering taking part in this study.

Please keep this information sheet for your own records.



University Hospital Southampton NHS Foundation Trust

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Data protection privacy notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

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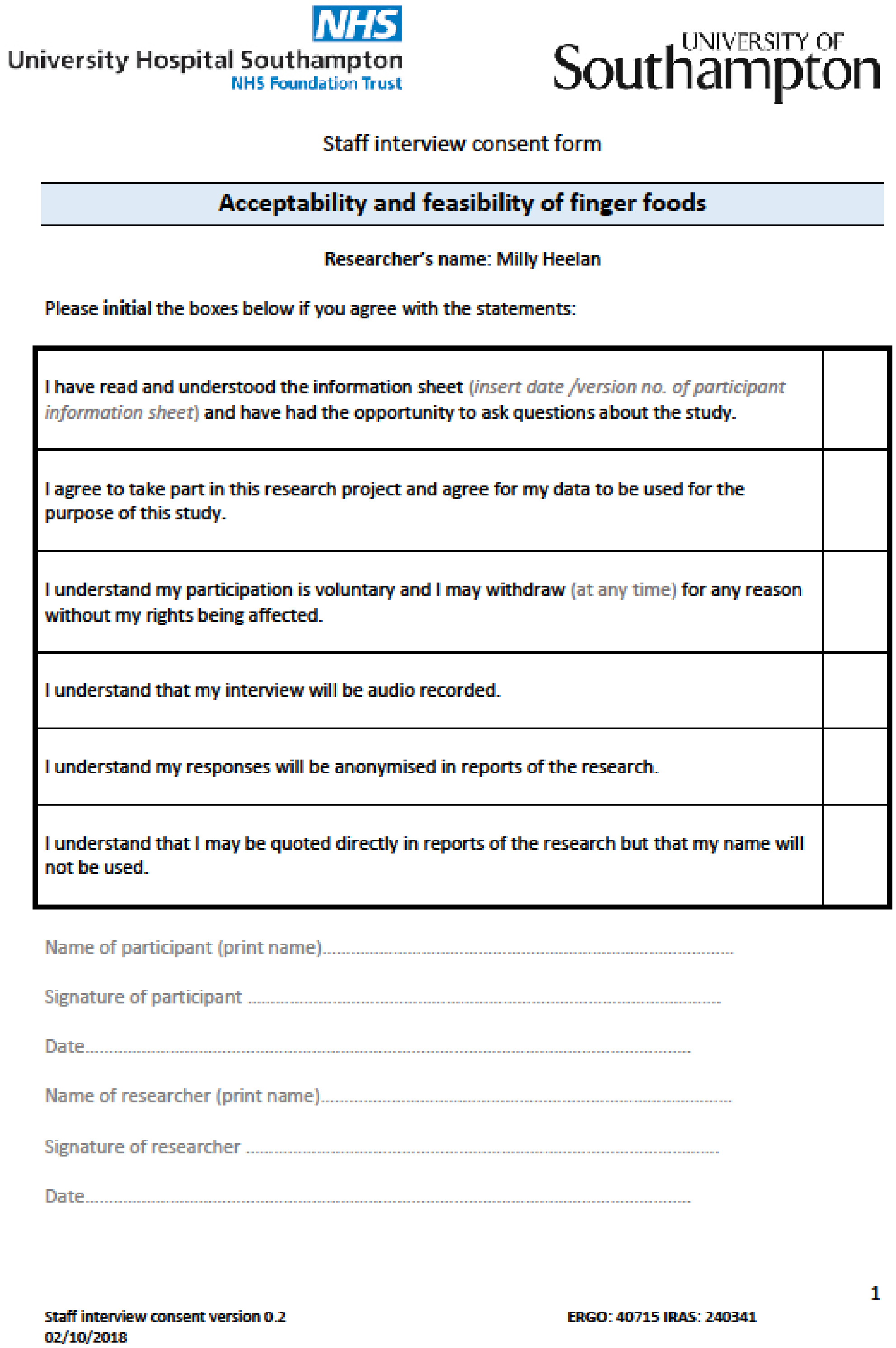
Appendix O Staff consent form



University Hospital Southampton NHS Foundation Trust

UNIVERSITY OF Southampton

Staff interview consent form

Acceptability and feasibility of finger foods

Researcher's name: Milly Heelan

Please initial the boxes below if you agree with the statements:

I have read and understood the information sheet *(insert date /version no. of participant information sheet)* and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw (at any time) for any reason without my rights being affected.	
I understand that my interview will be audio recorded.	
I understand my responses will be anonymised in reports of the research.	
I understand that I may be quoted directly in reports of the research but that my name will not be used.	

Name of participant (print name)……………………………………………………………………

Signature of participant ……………………………………………………………………………

Date……………………………………………………………………………………………………

Name of researcher (print name)……………………………………………………………………

Signature of researcher ……………………………………………………………………………

Date……………………………………………………………………………………………………

1

Staff interview consent version 0.2
02/10/2018

ERGO: 40715 IRAS: 240341

Appendix P Demographic data collection tool

Date consented
Study ID number
Bed number
Date of admission DD/MM/YY
Age
Gender
NIHS score
1 Level of consciousness appearance
2 LOC questions
3 LOC commands
4 Best gaze
5 Visual fields
6 Facial palsy
7 Motor arm right and left
8 Motor leg right and left
9 Limb ataxia
10 Sensory
11 Language
12 Dysarthria
13 Extinction and inattention
Evidence of cog impairment/dementia
Allergies/dietary requirements
Input from dietetic team
Weight at admission
Height at admission

BMI	
MUST score	

Appendix Q Interrater reliability guide to plate waste estimation

Interrater reliability assessment – Hospital meals

Thank you very much for agreeing to support with this research study.

This part of the study is looking at patient's food consumption of hospital meals by measuring plate waste. Plate waste is the food provided but not consumed by the patient and is an important measure of food consumption. It is important to measure food consumption to answer questions about nutrition and effectiveness of dietary interventions.

Plate waste can be measured using visual estimation. Visual estimation requires observers to rate each food item left on a patient's tray. In this method, the rater indicates the proportion of the menu item remaining on the plate: 0%, 25%, 50%, 75%, 90% or 100%. This rating is undertaken for each meal component.

For this study, digital photographs of hospital meal trays have been taken before the meal was provided to the patient and then after the patient had finished eating. This enables the rater to observe the size of the original serving of each food item and then to make a judgement regarding the proportion left on a patient's meal tray.

It is important that 2 different observers conduct the visual estimation, so that we can ensure that the data collected are reliable. The researcher of this study has already undertaken this task.

In the drop box file, you will find a spreadsheet for you to record values and lots of digital images for you to review.

The images are stored in the following format:

PHO_000_2019_02_09_A

- The first three numbers relate to the participant number
- Next, the date the photo was taken (YYYY_MM_DD)
- The letter at the end will either be an A or B. 'A' reflects photos taken before a mealtime and 'B' reflects photos taken after the mealtime.

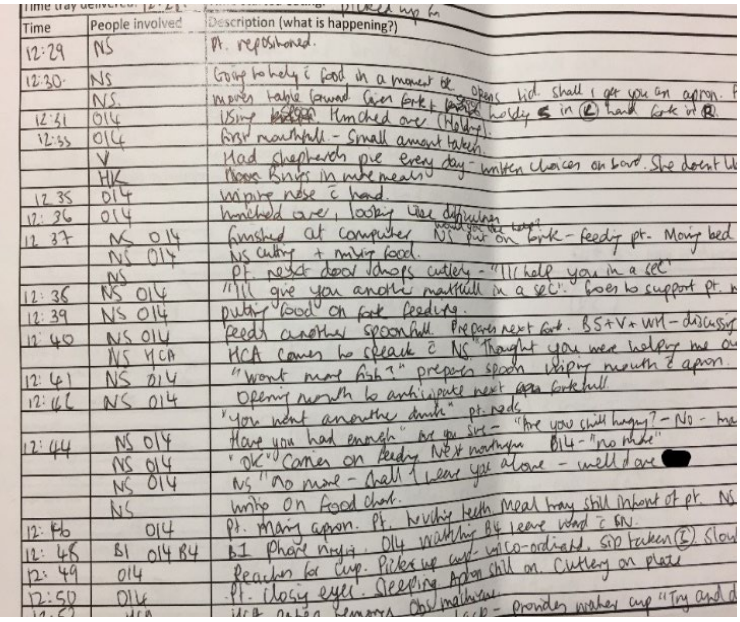
Appendix Q

On the spreadsheet provided for you to fill in values, the first column indicates the photos name. Subsequent columns indicate the food type. There is a column containing a drop-down bar for you to record how much of each food type has been eaten from each individual photo. There is a choice of 6 options:

- 100% - Full food portion remains on the plate
- 90% - Nearly full portion remains on the plate, but at least one bite has been taken
- 75% - If three quarters of the food portion remains
- 50% - Half of the food portion remains on the plate
- 25% - If one quarter of the food portion remains on the plate
- 0% - If none of the food portion remains

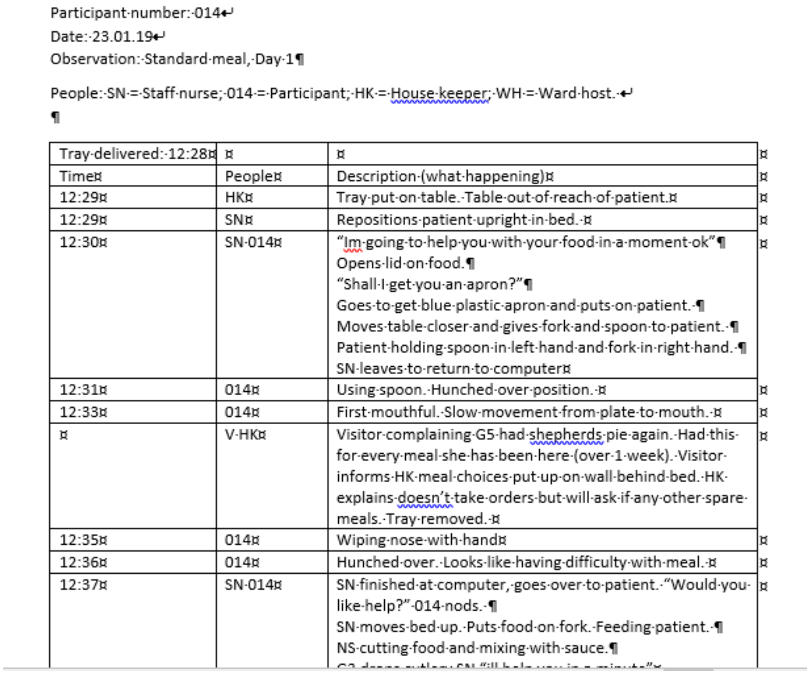
Appendix R Field notes from mealtime observations

Observational field notes were hand-written on the ward and then typed as seen below. Field notes were often written in short-hand and then expounded when typed in Microsoft word.



Time tray delivered: 12:2[illegible] picked up for

Time	People involved	Description (what is happening?)
12:29	NS	Pt. repositioned.
12:30	NS	Going to help ĉ food in a moment ok. Opens lid. Shall I get you an apron.
	NS.	moves table forward. Gives fork + spoon holding S in Ⓛ hand fork in Ⓡ.
12:31	014	Using ~~[illegible]~~ spoon. Hunched over (Holding).
12:33	014	First mouthful - Small amount taken.
	V	Had shepherds pie every day - written choices on board. She doesn't
	HK	[illegible] Brings in more meals
12 35	014	wiping nose ĉ hand.
12: 36	014	hunched over, looking like difficulties
12 37	NS 014	finished at computer would you like help? NS put on fork - feeding pt. Moving bed
	NS 014	NS cutting + mixing food.
	NS	Pt. next door drops cutlery - "I'll help you in a sec"
12:36	NS 014	"I'll give you another mouthfull in a sec". Goes to support pt.
12:39	NS 014	putting food on fork feeding.
12:40	NS 014	feeds another spoonfull. Prepares next fork. BS+V+WH - discussing
	NS HCA	HCA comes to speak ĉ NS "Thought you were helping me ou
12:41	NS 014	"want more fish?" prepares spoon wiping mouth ĉ apron.
12:4[illegible]	NS 014	Opening mouth to anticipate next [illegible] forkfull.
		"You want another drink" pt. nods "Are you still hungry? - No - ma
12:44	NS 014	"Have you had enough" are you sure - Next mouthful 014 - "no more"
	NS 014	"OK" Carries on feeding alone - well done [redacted]
	NS 014	NS "no more - shall I leave you
	NS	writes on food chart.
12:46	014	Pt. moving apron. Pt. touching teeth. Meal tray still infront of pt. NS
12:48	B1 014 B4	B1 Phone ringing. 014 watching B4 leave ward ĉ SN. uncoordinated. Sip taken Ⓘ. Slow
12:49	014	Reaches for cup. Picks up cup. Apron still on. Cutlery on plate
12:50	014	Pt. closing eyes. Sleeping. Obs machine
12:5[illegible]	HCA	HCA [illegible] removes [illegible] - provides water cup "Try and d



Participant number: 014
Date: 23.01.19
Observation: Standard meal, Day 1

People: SN = Staff nurse; 014 = Participant; HK = House keeper; WH = Ward host.

Tray delivered: 12:28		
Time	People	Description (what happening)
12:29	HK	Tray put on table. Table out of reach of patient.
12:29	SN	Repositions patient upright in bed.
12:30	SN 014	"Im going to help you with your food in a moment ok" Opens lid on food. "Shall I get you an apron?" Goes to get blue plastic apron and puts on patient. Moves table closer and gives fork and spoon to patient. Patient holding spoon in left hand and fork in right hand. SN leaves to return to computer
12:31	014	Using spoon. Hunched over position.
12:33	014	First mouthful. Slow movement from plate to mouth.
	V HK	Visitor complaining G5 had shepherds pie again. Had this for every meal she has been here (over 1 week). Visitor informs HK meal choices put up on wall behind bed. HK explains doesn't take orders but will ask if any other spare meals. Tray removed.
12:35	014	Wiping nose with hand
12:36	014	Hunched over. Looks like having difficulty with meal.
12:37	SN 014	SN finished at computer, goes over to patient. "Would you like help?" 014 nods. SN moves bed up. Puts food on fork. Feeding patient. NS cutting food and mixing with sauce.

Figure A-1 Example of handwritten and typed observational field notes

Alongside field notes, a diagram of the ward bay was recorded to show where the participant and researcher was positioned during the observation. The blue rectangles represent patient beds. V represents where there was a visitor present. SN in a triangle represents the location of the staff nurse for the majority of the observation. The yellow circle represets where the reseacher was located.

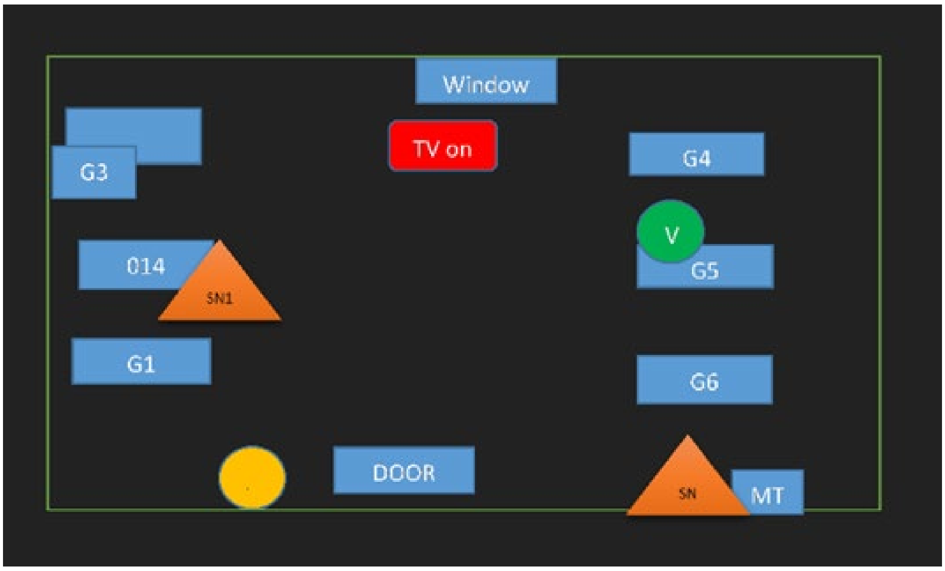


Figure A-2 Example of drawing to accompany observational fieldnotes

Appendix S Audit trail for qualitative interview data

An audit trail is described as a transparent description of the steps taken from the start of the research project to the development and report of the research findings. Audit trails can be used to establish the confirmability of a study (Lincoln and Guba 1985). Lincoln and Guba (1985) describe the categories for reporting information when developing an audit trail as proposed by Halpern (1983). These include:

- Materials related to intentions and dispositions, including reflexive notes and motivations
- Instrument development information, including schedules and pilot forms.
- Raw data
- Data reduction and analysis notes, including summary and theoretical notes
- Process notes, including methodology notes

Reflexive memos have been referred to throughout the thesis and further in Appendix E to describe the insider outsider reflections of the PhD candidate who undertook this research. The audit trail in Appendix S is used to present the interview schedules and further detail to show how the researcher generated themes from raw interview data.

Researcher and reflexivity

A solo, female PhD candidate conducted this study. The PhD candidate has a BSc undergraduate degree in Speech and Language Therapy. At the time of carrying out the study, the PhD candidate had a Clinical Doctoral Research Fellowship role, in which she was employed as a SLT for two days per week and PhD student conducting this research for three days per week. The PhD candidate carried out data collection for the study at the hospital she was employed. She had previous experience working on the study ward where the data collection was carried out. However, during the data collection period, she was working on other wards within the hospital. Having experience of working on the ward, the staff on the ward were familiar with the PhD candidate and aware of her clinical role. During data collection periods, the PhD candidate made her role as a researcher explicit. The PhD candidate has attended a five-day course on conducting and analysing qualitative research and has previous experience of supporting thematic analysis of another research study.

Appendix S

Interview schedules

A semi structured interview schedule was used for all interviews. Schedules were adjusted for patients and staff. Prompts were used throughout interviews to complement the schedule, such as ‘can you elaborate on that’.

Patient participant interview schedule

1. Mealtime experience - How did you find eating your lunch today? Was there anything you liked or didn’t like?
2. Mealtime access – How did you find eating and accessing the food? What did you use? Do you normally have help with eating? Did you have help today?
3. Meal quality – What do you think of how the food looked? What was the temperature of the food like? Tell me about the taste and nutritional value of the food?
4. Would you like to try these types of foods again? Why?
5. Do you have any thoughts about the safety of eating these foods?
6. Some people have shown concerns about eating with their fingers. What do you think?

Staff interview schedule

1. Why did you decide to take part in this study?
2. What is your role within the hospital at mealtimes?
    - How long have you worked in this role?
    - How do you work with hospital staff/catering team?
    - How do you think patients feel at mealtimes?
    - How do you think relatives think about mealtimes on this ward?
3. Are you aware of the finger food project that ran on the ward? Can you tell me what happened during the study? Ordering, preparing, etc
4. Mealtime experience - Can you tell me about a mealtime you remember when a patient has eaten finger foods/eaten with hands?
   Were there any comments or actions made by patients regarding eating with their fingers? What went well? What didn’t go so well?
5. Mealtime access – How did the patients eat the “finger food”? What support do patients have if they have difficulty eating? Did you help patient with finger food? How do you feel about patients using of hands for eating? How do you think using finger foods fits in with the rehab process?
6. Meal quality – What do you think of how the food looked as finger food? Tell me about any comments made by patients regarding the temperature/taste/nutritional value.
    - Additional preparation of food required?
7. Do you think we should offer them to all patients?
8. Do you think they worked better for a specific group of patients?
9. Any experience of using these types of foods elsewhere in different setting? Different ward in this hospital?

Thematic analysis supported by NVivo

Reflexive thematic analysis was used to analyse interview transcripts as per Section 4.10.3.2.

Initially, audio files were re-listened to and transcripts re-read to enhance familiarisation. Line by line coding in NVivo as per Figure A-3 was conducted to find initial descriptive elements of interest. Staff and patient interviews were coded separately to ensure that views from each participant group could be analysed individually.

INT: Yeh... And how do you feel about having him help you?

095: No problems whatsoever. If he wasn't here I think I would be panicking a bit. to have someone a presence of somebody that is a friend or a relative... umm... es mealtimes. And that's the other thing, like (husband) said you have to learn to fee eventually, cos you are going to go out to a restaurant or something aren't you so just have... anything that I can pick up with my fingers (laughing).

INT: Yeh definitely, in that sense it's good to get practising with the cutlery

095: So yes, you can't always eat finger food (laughing). But I had the pizza yester delicious. I really, really enjoyed that.

INT: That was a good one ---

095: --- Yeh that was a good change. The goujons that I had, they came but, they cold.

INT: OK...

095: But no generally, I don't have any problems with food, one way or the other.

Figure A-3 Line by line coding using NVivo

As seen in Figure A-3, some lines of data had overlapping codes. Where overlaps existed, codes were condensed and grouped by description. An example of descriptive codes that were generated relating to interview participants is presented in Table A-1.

Appendix S

Table A-1 Participant number and related codes

Code	Participant number (Patient)											
	003	006	018	037	055	056	057	077	080	084	091	095
Visual appearance of finger food	x	x	x	x				x	x			
Ease of using hands		x			x		x	x	x	x		x
Practically cleaning hands prior to eating					x							x
Risks of dropping food		x						x				
Using cutlery to eat finger food	x			x			x	x	x			x
Food quality					x			x				
Managing soft foods				x	x					x		
Colour and freshness impacting on presentation of food	x	x	x	x				x	x			
Size, shape of finger food			x		x		x	x		x		
Stodgy food texture										x		
Swallowing difficulties impacting on eating										x		
Personal tastes		x			x							
Timing making food cold		x		x				x				x

Warm food tastes nicer							x					x

Code	Participant number (Staff)										
	023	024	026	066	067	072	083	086	093	094	100
Patients enjoying finger foods					x					x	
Visual appearance - colours impact on presentation									x		
Convincing of a homemade product	x										
Finger food interesting and enticing			x	x			x		x		
Finger foods are easy to eat				x			x	x			x
Finger foods are foods people normally eat		x	x				x	x	x	x	
Finger food as bitesize food						x					
Pre-designed finger foods would make a difference			x					x	x		

To aid organisation, the descriptive codes were reviewed to notice similarities and overlaps and combined to create categories. Table A-2 displays categories that were generated from patient interview data and staff interview data. At this point, similarities between patient and staff categories were noted. Categories were re-ordered and clustered based upon meaning. Due to the parallels and similarities drawn from patient and staff interviews, it was agreed with the supervisory team that overarching themes would be generated to represent data from both patient and staff interviews.

Table A-2 Categories generated from patient and staff interviews

Categories from patient interviews	Categories from staff interviews
• Appeal of finger food • Texture, temperature and taste • Food choices • Needing enough options • Nutritional value of finger food • Changes in appetite • Patients receiving support with eating • Relying on family support • Staff assisting with mealtime tasks • Practicalities of using finger foods • Accessing food • Finger foods are easier to manage and avoid mess • Striving for independence • Enabling patient's mealtime traditions • A journey through different stages/phases • Stroke symptoms impacting on eating • Finger food needs to be presented appropriately • Fitting in with hospital routines • Honouring hand hygiene	• Appeal of finger food for different generations • Appearance of finger food • Nutritional value of finger food • Family providing social and physical mealtime assistance • Patient reliance on mealtime support • Task orientated staff assistance at mealtimes • How patients access food in hospital • Finger foods are easier to manage • Challenges to using finger foods in hospital • Unique patient mealtime preferences • Relationships between hospital mealtimes and home routines • Potential benefits of finger foods • Rehabilitation of eating behaviours • Serving of finger food • Considerations for future finger food menu development • Supporting changes to catering service/training needs

Based on the categories presented from both patient and staff interviews, tables were created through framework matrices in NVivo 12 (QSR International 2020), as shown in Figure A-4. For each category, frameworks presented the raw data from patient and staff interviews and descriptive codes relating to the category. Themes were generated to depict what was said by both patients and staff and to reflect the raw data.

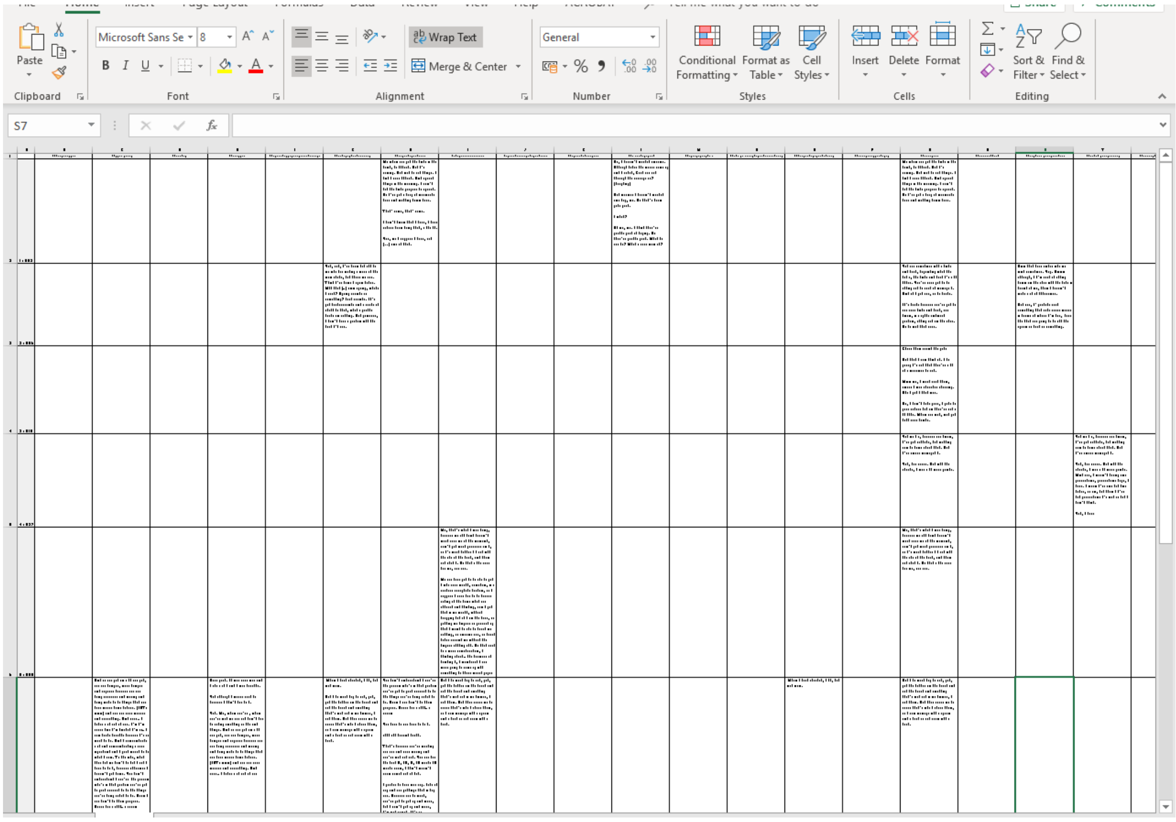


Figure A-4 Example matrix made using NVivo

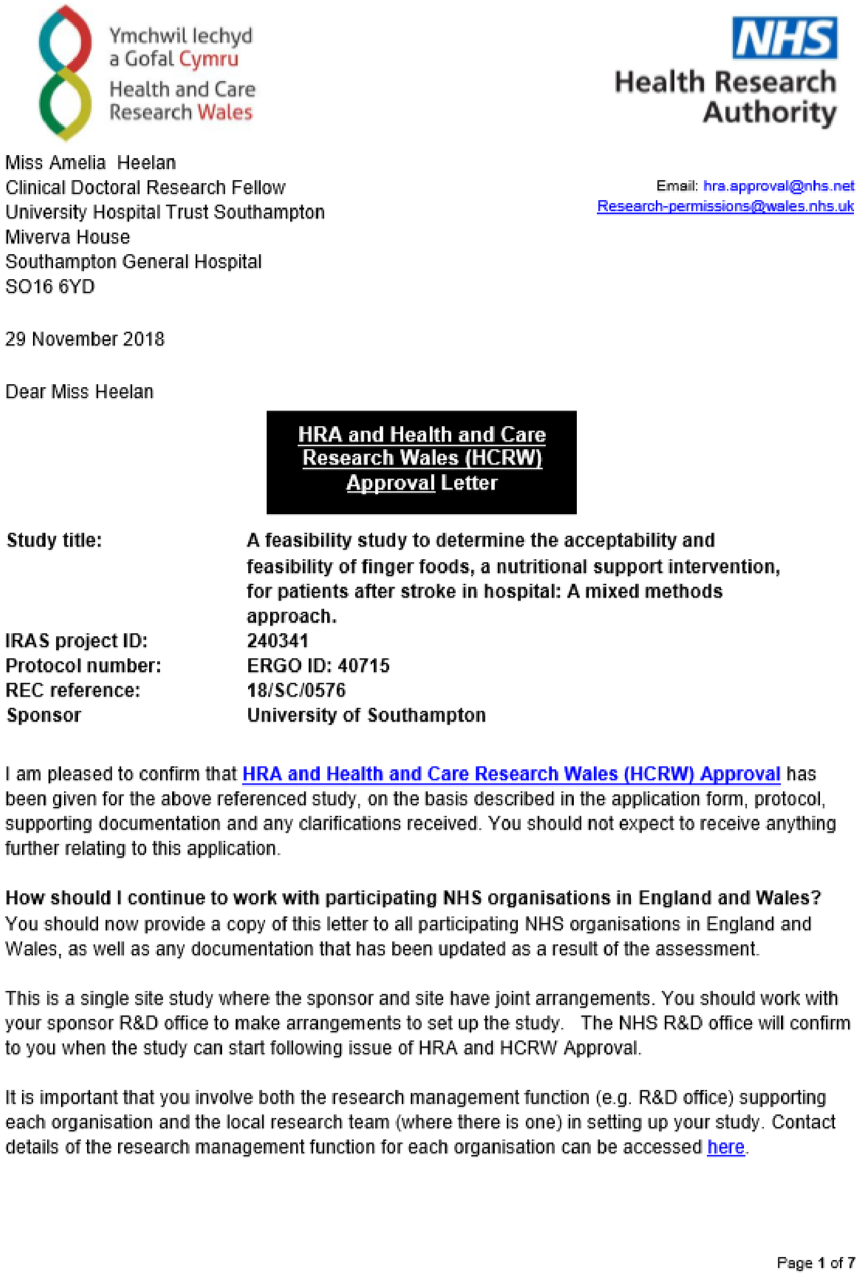
These themes were then reviewed, by relating back to the raw text and refined, defined and named. Table A-3 shows an example of the analysis process displaying movement from quotes to codes, categories and themes. At this stage ‘Twenty questions to guide assessment of TA research quality’, published on The University of Auckland website (The University of Auckland Unknown date) and recently published in Qualitative research in psychology (Braun and Clarke 2021), was used to reflect on the analysis process by the PhD researcher. During reflection of point 16 “Is a non-thematic contextualising information presented as a theme?”, the PhD candidate identified the engagement of participants as contextual information which was subsequently presented as a non-thematic contextualising theme. Final themes generated from interviews are presented in section 6.4, with further description of the theme, narration and quotes extracted from interview transcripts

Appendix S

Table A-3 Moving from direct participant quote to theme

Quote	Code	Category (subtheme)	Theme
"Yeah I think when you are older, you don't want too much chewy food" (Participant 037 - Patient)	Managing soft foods	Texture, temperature and taste	Visual appeal
"I don't know… it was hot, it was lovely. It was like the deep crust one. The topping was lovely. Really moist, really tomatoey and cheesy" (Participant 095 - Patient)	Warm food tastes nicer	Texture, temperature and taste	Visual appeal
"I really, really liked the pizza, and that was so simple. Cos it didn't come with anything that I had to worry about." (Participant 095 – Patient)	Ease of using hands	Finger foods are easier to manage Practicalities of using finger foods	Visual appeal
"Side Room 1 she quite enjoys her finger foods and you always see that patient that picks up like always chooses a sandwich because it's easy for them to eat and like I said older people, their appetite is not great anyway, is it, so they do choose a sandwich because it's light." (Participant 026 - Health Care Assistant)	Finger foods are easy to eat	Finger foods are easier to manage Practicalities of using finger foods	Visual appeal

Appendix T Ethics approval



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Miss Amelia Heelan
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29 November 2018

Dear Miss Heelan

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**A feasibility study to determine the acceptability and feasibility of finger foods, a nutritional support intervention, for patients after stroke in hospital: A mixed methods approach.**
IRAS project ID:	**240341**
Protocol number:	**ERGO ID: 40715**
REC reference:	**18/SC/0576**
Sponsor	**University of Southampton**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

This is a single site study where the sponsor and site have joint arrangements. You should work with your sponsor R&D office to make arrangements to set up the study. The NHS R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

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Appendix U Participant characteristics (patient)

Participant ID	Age category	Gender	NIHS score
003	80+	Female	Minor stroke
004	80+	Male	No symptoms
006	80+	Male	Minor stroke
007	65 -80	Female	Moderate stroke
012	80+	Male	Moderate stroke
013	65 -80	Male	Minor stroke
014	80+	Female	Moderate-severe stroke
018	80+	Female	Minor stroke
019	65 -80	Male	Moderate stroke
028	65 -80	Female	Minor stroke
031	80+	Female	Moderate stroke
033	80+	Female	Moderate stroke
037	80+	Female	Minor stroke
040	65 -80	Female	Moderate-severe stroke
042	65 -80	Female	Moderate stroke
045	65 -80	Male	Minor stroke
047	80+	Male	Minor stroke
055	80+	Male	Minor stroke
056	80+	Female	Moderate stroke
057	65 -80	Male	Moderate stroke
059	80+	Female	Moderate stroke
064	65 -80	Male	Minor stroke

071	80+	Male	Minor stroke
077	80+	Male	Moderate stroke
079	65 -80	Male	Minor stroke
080	65 -80	Female	Moderate stroke
084	65 -80	Male	Moderate stroke
088	80+	Female	Moderate stroke
090	80+	Female	No symptoms
091	65 -80	Male	Moderate-severe stroke
095	65 -80	Female	Moderate-severe stroke

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